UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT CHATTANOOGA

In Re: Skelaxin (Metaxalone) Antitrust Litigation This Document Relates To: ALL END-PAYOR ACTIONS	Lead Case No. 1:12-cv-194 MDL Case No. 1:12-md-2343 Judge Curtis L. Collier

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CONSOLIDATED CLASS ACTION COMPLAINT

Plaintiffs United Food and Commercial Workers Union and Midwest Health Benefits Fund ("UFCW"), Pirelli Armstrong Retiree Medical Benefits Trust ("Pirelli"), Allied Services Division Welfare Fund ("ASD"), Plumbers and Pipefitters Local 572 Health and Welfare Fund ("Local 572"), Laborers Trust Fund for Northern California ("Laborers"), and Louisiana Health Service Indemnity Company ("BCBSLA") (collectively, "Plaintiffs"), on behalf of themselves and all others similarly situated, for the Consolidated Complaint against Defendants King Pharmaceuticals, Inc. ("King") and Mutual Pharmaceutical Company, Inc. ("Mutual") (collectively, "Defendants"), allege as follows based on (a) personal knowledge of those matters relating to themselves, (b) the investigation of their counsel, including the review of publicly available pleadings, court orders, and other public filings concerning the conduct at issue in this action, and (c) information and belief.

I. INTRODUCTION

1. Plaintiffs bring this antitrust action on behalf of a Class of end-payors that indirectly purchased or reimbursed for the prescription drug Skelaxin, a muscle relaxant containing the active ingredient Metaxalone, or its AB-rated generic bioequivalents. Plaintiffs seek to recover overcharge damages incurred by the Class due to Defendants' anticompetitive conduct, which delayed entry of less expensive generic versions of Skelaxin. Defendants' anticompetitive scheme is a violation of federal and state antitrust laws, state consumer protection and deceptive business practices laws, and state unjust enrichment laws.

2. Although the original compound patent for Skelaxin expired in 1979, generics remained foreclosed from the market until April 9, 2010, over thirty years later. The Defendants

illegally delayed generic entry by implementing an overarching anticompetitive scheme, including the following acts:

a. Defendant King initiated and perpetuated baseless sham patent litigation against generic competitors to enforce United States Patent No. 6,407,128 (the "'128 Patent"), No. 6,683,102 (the "'102 Patent"), which patents King wrongfully listed and/or continued to list in the "Orange Book" published by the United States Food and Drug Administration ("FDA"), and filed baseless citizen petitions with the FDA;

b. Defendants entered into an unlawful market allocation agreement that exceeded the legitimate exclusionary scope of the relevant patents, pursuant to which Mutual agreed not to launch a generic version of Skelaxin in the United States in exchange for payments by King that have exceeded $200 million to date (the "King-Mutual conspiracy");

c. King and Mutual, in furtherance of the King-Mutual conspiracy, failed to advise a federal court that the dispute between them had been resolved and instead requested that the court stay the litigation in order to delay a decision on the validity of key patents, thus creating a false appearance to the court, the FDA, and the Federal Trade Commission ("FTC") that Mutual was vigorously attempting to bring a competing drug to market;

d. Pursuant to the King-Mutual conspiracy, Defendants engaged in a campaign of filing numerous meritless citizen petitions with the FDA with the sole purpose of thwarting and delaying other companies' efforts to obtain FDA approval of generic versions of Skelaxin, and, in so doing, unlawfully extended King's

monopoly over metaxalone products years beyond the point at which generic competition would otherwise have ensued; and

e. King and Mutual, pursuant to the King-Mutual conspiracy, initiated and perpetuated baseless sham patent litigation against a generic competitor to enforce United States Patent No. 7,122,566 (the '566 Patent), which they wrongfully listed and/or continued to list in the Orange Book.

3. The scheme worked as planned; generic Skelaxin was not sold until on or about April 9, 2010, far later than it would have been absent Defendants' illegal, anticompetitive conduct.

4. Because of Defendants' scheme to delay generic Skelaxin competition, in whole or in part, Plaintiffs and the Class have paid hundreds of millions of dollars more for metaxalone products than they would have paid absent such conduct.

II. JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds $5,000,000, there are more than one hundred members of the Class, and at least one member of the putative Class is a citizen of a state different from that of one of the Defendants.

6. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiffs bring claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendants' violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2. The Court has supplemental jurisdiction over Plaintiffs' pendent state law claims pursuant to 28 U.S.C. § 1367.

7. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §1391(b) and (c), because Defendants transact business within this district, and because the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district.

III. PARTIES

8. Plaintiff UFCW is an "employee welfare benefit plan." UFCW's office responsible for covering medical benefits, including benefits for prescription drugs, is located in Cook County, Illinois. During the Class Period, as defined below, UFCW purchased and/or provided reimbursement for brand Skelaxin or its generic equivalent in Florida, Iowa, Illinois, Indiana, and Oklahoma. UFCW paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry.

9. Plaintiff Pirelli is a voluntary employee benefits association maintained pursuant to the federal Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1132, *et seq.* Pirelli maintains its principal place of business in Goodlettsville, Sumner County, Tennessee. During the Class Period, as defined below, Pirelli purchased and/or provided reimbursement for brand Skelaxin or its generic equivalent in Alabama, Arizona, California, Florida, Iowa, Illinois, Kentucky, Mississippi, Oregon, Tennessee, and Texas. Pirelli paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry

10. Plaintiff ASD is a health and welfare benefit fund with its principal place of business at 53 West Seegers Road, Arlington Heights, Illinois 60005. During the Class Period, as defined below, ASD purchased and/or provided reimbursement for brand Skelaxin or its generic equivalent in Alabama, Arizona, Florida, Georgia, Illinois, Kansas, Louisiana, Massachusetts, Minnesota, Missouri, Mississippi, Nebraska, New Jersey, Ohio, Oklahoma,

Pennsylvania, Rhode Island, Tennessee, Texas, Utah, and Virginia. ASD paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry.

11. Plaintiff Local 572 is a trust fund administered pursuant to the Taft-Hartley Act, 29 U.S.C. § 186, by an equal number of trustees appointed by labor representatives and union representatives; Local 572 is an "employee welfare benefit plan" maintained pursuant to Section 302(c)(5), and as defined by Sections 1002(1) and (3) of ERISA, 29 U.S.C. § 1001, *et seq*. Local 572 maintains its office in Davidson County, Tennessee. During the Class Period, as defined below, Local 572 purchased and/or provided reimbursement for brand Skelaxin or its generic equivalent in Alabama, Mississippi, and Tennessee. Local 572 paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry.

12. Plaintiff BCBSLA is a domestic health insurance corporation involved in the business of providing health benefits to covered lives. BCBSLA is licensed to conduct business in the State of Louisiana. During the Class Period, as defined below, BCBSLA purchased and/or provided reimbursement for brand Skelaxin or its generic equivalent in Alabama, Arizona, Arkansas, California, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, and West Virginia. BCBSLA paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry.

13. Plaintiff Laborers is a trust fund administered pursuant to the Taft-Hartley Act, 29 U.S.C. § 186, by an equal number of trustees appointed by labor representatives and union representatives; Laborers is an "employee welfare benefit plan" maintained pursuant to Section 302(c)(5), and as defined by Sections 1002(1) and (3) of ERISA, 29 U.S.C. § 1001, et seq.

Laborers maintains its office in Fairfield, California. During the Class Period, as defined below, Laborers purchased and/or provided reimbursement for brand Skelaxin or its generic equivalent in Arizona, California, Hawaii, Nevada and West Virginia. Laborers paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry.

14. Defendant King is a corporation organized and existing under the laws of the state of Tennessee with its principal place of business at 501 5th Street, Bristol, Tennessee 37620.

15. Defendant Mutual is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania with its principal place of business located at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124.

16. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or performed by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs, within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

IV. REGULATORY BACKGROUND – GENERIC DRUG APPROVAL PROCESS

A. Generic drugs benefit purchasers.

17. Generic competition enables purchasers, at all levels of the pharmaceutical supply chain, to (a) purchase generic versions of the brand name drug at a substantially lower price than the brand name drug, and (b) purchase the brand name drug at a reduced price. Generic competition to a single branded drug product can result in billions of dollars in savings to consumers, insurers, pharmacies, and other drug purchasers.

18. Orally available generic solid dosage forms (tablets, capsules, etc.) that meet all of the requirements for approval, are assigned an "AB" rating by the FDA. The "AB" rating permits the generic drug to be substituted for the brand name drug at the pharmacy counter.

19. All states permit (and some states require) pharmacists to automatically substitute an AB-rated generic drug for the corresponding brand name drug unless the doctor has stated that the prescription for the brand name product must be dispensed as written. Until a generic manufacturer enters the market, no substitution can occur, and the brand name manufacturer can therefore charge supracompetitive prices profitably without material loss of sales volume to generics. Consequently, brand name drug manufacturers have a strong interest in seeking to delay the market entry of generic competition.

20. Many third party payors (such as health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. In addition, many consumers routinely switch from a branded drug to an AB-rated generic drug once the generic becomes available. Consequently, AB-rated generic drugs typically capture a significant share of their branded counterparts' sales, causing a significant reduction of the branded drug's unit and dollar sales.

21. Typically, the first AB-rated generic drug is priced significantly below its branded counterpart. Upon the entry of additional AB-rated generics, also priced much less than their branded counterparts, drug prices generally decline, falling further over time, as more generic equivalents compete with each other.

22. Once a generic equivalent hits the market, the generic quickly captures sales of the branded drug, often capturing 80% or more of the market within the first six months.

23. Brand manufacturers are well aware of generics' rapid erosion of their previously monopolized market. Branded manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible – including illegal means.

B. The FDA oversees new drug approvals and allows manufacturers to list, but does not check the validity of, applicable patents covering their products in the Orange Book.

24. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers who create a new drug product must apply for FDA approval to sell the new drug by filing a New Drug Application ("NDA").[1] An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.[2]

25. Once an NDA has been approved, the manufacturer may also file supplemental New Drug Applications ("sNDAs") to seek approval for changes to its drug or label after obtaining FDA approval for the drug.

26. When the FDA approves a brand name manufacturer's NDA, the brand manufacturer lists all patents that cover its product (*i.e.*, could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug) in the FDA's "Orange Book," or book of Approved Drug Products with Therapeutic Equivalence Evaluations.[3] New patents obtained after NDA approval must be listed in the Orange Book as related to the NDA if the new patent claims either the approved drug (for compound patents) or approved methods of use for the approved drug (for method-of-use patents). The NDA holder is

[1] 21 U.S.C. §§ 301-392.

[2] *Id*. at §§ 355(a) & (b).

[3] *Id*. at §§ 355 (b)(1) and (c)(2).

required to file information on any such patent with the FDA within thirty days of the patent's issuance.[4]

27. The FDA relies completely on the brand manufacturer's truthfulness about a patent's validity and applicability; the FDA lacks the statutory authority and the resources to evaluate the validity of the patent. The FDA performs a ministerial function in listing patents in the Orange Book.

28. With respect to patents that have method-of-use claims, the NDA holder is obligated to submit patent information that includes "use codes" with specific descriptions of the protected methods-of-use.[5] "Use codes" are listed in the Orange Book and are intended to alert potential generic competitors to patents that claim an approved use for the relevant drug. "Use code narratives" are written descriptions, provided by the NDA holder, of the approved method-of-use claimed by a patent.

C. The federal government encourages and facilitates the approval of generic drugs through Hatch-Waxman.

29. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments to the FDCA, changed the approval standards for generic drugs.[6] Through the Hatch-Waxman Amendments, Congress sought to expedite the market entry of generic drugs, thereby reducing healthcare expenses nationwide. Congress also wanted to protect pharmaceutical companies' incentives to create new and innovative products.

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[4] *Id*. at §§ 355 (b)(1) and (c)(2).

[5] 21 CFR §§ 314.53(b) and (c).

[6] *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

30. A generic manufacturer seeking approval to sell a generic version of a brand name drug may file an Abbreviated New Drug Application ("ANDA"). If an ANDA applicant shows that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug – that is, that the generic drug is "bioequivalent" to the brand name drug – then the ANDA may rely on the scientific safety and effectiveness findings included in the brand name drug manufacturer's original NDA. The FDA assigns an "AB" rating to generic drugs that are bioequivalent to branded drugs.

31. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products are therapeutically equivalent and may be substituted for one another when the products: (1) contain identical amounts of the same active ingredients in the same route of administration and dosage form; (2) meet applicable standards of strength, quality, purity and identity; (3) are manufactured in compliance with current good manufacturing practices regulations; and (4) are adequately labeled. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart.[7]

1. Generic drugs must be bioequivalent to their branded counterparts.

32. The Hatch-Waxman Amendments created section 505(j) of the FDCA and established the current ANDA approval process.[8] To obtain approval, an ANDA applicant is not required to submit evidence on the clinical safety and effectiveness of the drug product; instead, an ANDA relies on the FDA's previous finding that the reference listed drug (or "RLD", the brand drug) is safe and effective. To rely on a previous finding of safety and effectiveness, an

[7] 21 U.S.C. § 355(j)(8)(B).

[8] *Id*. at § 355(j).

ANDA applicant must demonstrate, among other things, that its drug product is bioequivalent to the RLD.[9] In addition, an ANDA must contain, with certain exceptions not relevant here, information to show that the proposed drug has the same active ingredient(s), indications of use, route of administration, dosage form, strength, and labeling as the RLD.[10] The FDA must approve an ANDA unless the information submitted in the ANDA is insufficient to meet the requirements delineated in § 505(j)(2)(A) of the Act, including a demonstration of bioequivalence.[11]

33. The Hatch-Waxman Amendments require that an ANDA contain "information to show that the labeling proposed for the new [generic] drug is the same as the labeling approved for the listed drug . . . except for changes required because of differences approved under a petition filed under [section 505(j)(2)(C) of the Act] or because the new drug and the listed drug are produced or distributed by different manufacturers."[12] A parallel provision appears in section 505(j)(4)(G) of the Act.[13] Information that is relevant to both the RLD and the generic drug must be in the labeling for the RLD before it is required to be incorporated in the labeling for an ANDA that references the RLD.

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[9] *Id*. at § 355(j)(2)(A)(iv).

[10] *Id*. at §§ 355(j)(2)(A), (j)(4).

[11] *Id*. at § 355(j)(4).

[12] 21 U.S.C. § 355(j)(2)(A)(v).

[13] *Id*. at § 355(j)(4)(G) (providing that FDA must approve an ANDA unless, among other things, "the information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for [the reference listed drug] except for changes required because of differences approved under [an ANDA suitability petition] or because the drug and the listed drug are produced or distributed by different manufacturers.").

34. FDA regulations in 21 CFR § 320 list acceptable methodologies for determining the bioequivalence of drug products. These methodologies include pharmacokinetic studies, pharmacodynamic studies, comparative clinical trials, and *in vitro* studies. The choice of which study design to use is based on the ability of the design to compare the drug delivered by the two products at the particular site of action of the drug. The courts have expressly upheld the FDA's regulatory implementation of the Act's bioequivalence requirements.[14]

35. *In vivo* pharmacokinetic tests measure the rate and extent of absorption in live subjects. (In comparison, *in vitro* tests measure the rate and extent of absorption in a controlled environment, not in live subjects.) For *in vivo* pharmacokinetic tests, the FDA generally considers two products to be bioequivalent when the 90 percent confidence intervals for the ratios of the pharmacokinetic parameters (area under the plasma concentration vs. time curve ("AUC") and maximum drug concentration ("Cmax")) are entirely within an 80 to 125 percent acceptance interval. The use of an 80 to 125·percent acceptance interval is a scientific judgment about the best statistical practices for bioequivalence determinations and reflects decades of scientific data on the variability of product characteristics within and between batches, as well as biological variability in patients. Because the mean of the study data lies in the center of the 90 percent confidence interval, the mean of the data is usually close to 100 percent (a test/reference ratio of 1).

[14] *See, e.g.*, *Schering Corp. v. FDA*, 51 F.3d 390 at 397-400 (3d Cir.1995); *Fisons Corp. v. Shalala*, 860 F. Supp. 859 (D.D.C. 1994).

2. Generic companies must certify that their product will not infringe the patents listed in the Orange Book.

36. To obtain FDA approval, an ANDA applicant must provide one of several certifications to the FDA and the patent holder regarding patents and other exclusivities covering the brand product. First, the generic manufacturer must certify that the generic drug will not infringe patents covering the drug, as listed in the Orange Book, because (I) no patents exist on the brand product; (II) any listed patents will have expired by the time the product comes to market; (III) the generic product will not come to market until the listed patents expire; or (IV) the listed patents are invalid or will not be infringed by the sale of the generic product.[15] The last certification, that the patents are invalid or not infringed, is known as a "Paragraph IV certification."

37. If a generic manufacturer files a Paragraph IV certification, it constitutes a technical act of infringement under the Hatch-Waxman Amendments even though the generic product is not yet on the market.[16] If the brand manufacturer sues within 45 days of receiving notification of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) the passage of thirty months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. The FDA may grant "tentative approval," but cannot authorize the generic manufacturer to go to market before the passage of thirty months or a court decision of invalidity or non-infringement.

[15] 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV).

[16] Although filing a Paragraph IV certification is a technical act of infringement under the statute, a patent holder that brings an infringement suit must still prove infringement on the merits to succeed in litigation.

38. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification gets a period of protection from competition with other generic versions of the drug. For Paragraph IV certifications made prior to December 2003, the first generic applicant is entitled to 180 days of market exclusivity, *i.e.*, all generics (other than one marketed by the branded manufacturer) are kept off the market for at least six months. When multiple generic applicants make the first Paragraph IV certifications with respect to different patents or file ANDAs on the same day, they are each entitled to shared exclusivity.

3. Generic companies may, with permission from the FDA, carve out portions of the branded drug's label.

39. In general, a generic must have the same label as its branded (RLD) counterpart. The Food, Drug, and Cosmetic Act requires that an ANDA contain "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a [listed drug]."[17] The Act also requires that an ANDA contain "information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug."[18]

40. A generic's label may omit aspects of the brand's label when that labeling is protected by a patent or other exclusivity: "Differences between the applicant's proposed labeling and labeling approved for the reference listed drug may include difference in expiration date, formulations, bioavailability, or pharmacokinetics … or omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(4)(D) of the

[17] *Id*. at § 355(j)(2)(A)(i).

[18] *Id*. at § 355(j)(2)(A)(v).

act."[19] However, the labeling differences may not render the generic less safe or effective than the listed drug.[20]

41. For listed patents that claim methods of use, the ANDA applicant may submit a Section VIII certification stating that the generic manufacturer is seeking approval for uses not covered by the patent, and that the patented use will be "carved out" of its label.[21]

42. When a generic manufacturer files an ANDA with a Section VIII "carve out" statement, the stay provision associated with ANDAs filed pursuant to Paragraph IV certifications does not apply. To the extent the brand manufacturer contends that the ANDA filer is infringing on a patent, the brand manufacturer can file an infringement suit, but it does not get the benefit of an automatic stay. Moreover, the generic manufacturer, even if it is the first to file an ANDA with respect to the brand product, does not get the benefit of 180 days of market exclusivity.

D. The FDA's citizen petition process allows persons to raise genuine issues of clinical therapeutic importance.

43. FDA regulations allow individuals to express genuine concerns about safety, scientific, or legal issues regarding a product any time before or after its market entry by submitting a citizen petition to the FDA. Under these regulations, any person or entity, including a pharmaceutical company, may file a citizen petition with the FDA requesting that the FDA

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[19] 21 CFR § 314.94(a)(8)(iv). *See also Bristol-Myers v. Shalala*, 91 F.3d 1493, 1500 (D.C. Cir. 1996) (upholding FDA's authority to approve generic drugs with labeling that omits information protected by exclusivity); *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002) (same re information protected by patent), *aff'd Purepac Pharm. Co. v. Thompson*, Nos. 02-5410 & 03-5121, 2004 WL 76594 (D.C. Cir. Jan. 20, 2004).

[20] 21 CFR § 314.127(a)(7).

[21] 21 U.S.C. § 355(j)(2)(A)(viii).

take, or refrain from taking, any administrative action.[22] The person or entity submitting such a citizen petition is required, under FDA regulations, to include all information and views on which the petitioner relies, as well as all information and data known to the petitioner which is unfavorable to the petition.

44. Federal regulations provide a 180-day period for the FDA to respond to each citizen petition.[23] However, the FDA usually takes much more than 180 days to do so because reviewing and responding to these petitions is often a resource-intensive and time-consuming task requiring the FDA, in addition to its already-existing workload, to: (a) research the citizen petition's subject matter; (b) examine scientific, medical, legal, public health and safety concerns, and occasionally economic issues; (c) consider public responses; and (d) coordinate internal agency review and clearance of the petition response.

45. These activities can and do strain the FDA's limited resources. It was the well-known practice of the FDA during the Class Period to consider and respond to a citizen petition prior to approving an ANDA product that was the subject of the citizen petition and to delay approval of the ANDA pending response to a citizen petition, particularly when the petition had been filed by a brand name pharmaceutical company arguing (whether correctly or not) a public health or safety concern.

E. This regulatory scheme is susceptible to abuse.

46. Brand companies have learned how to exploit this regulatory scheme to prolong generic entry beyond lawful limits. This section describes, in general terms, the regulatory features for these abuses and how they can lead to delayed generic competition.

[22] 21 CFR § 10.30.

[23] *See id*. at § 10.30(e)(2).

47. That these features can be, and have been, abused does not mean that Congress or the FDA sanctions this manipulation. To the contrary, both Congress and the FDA have acted to counter these abuses.

1. Brand companies abuse labeling requirements.

48. Although not intended to do so, the FDA statutes and regulations provide incentives for the brand company to needlessly change its labels.

49. Brand companies at times add language to their labels about features or methods of using the drug. In general, a would-be generic manufacturer's label must match the branded label; when the patented information appears on the brand label, the brand company might sue the would-be generic for patent infringement. As a result, when such language exists, a would-be generic company is required to go through a process with the FDA to "carve out" the branded company's language from the label. The process takes time, and brand companies often change labeling solely to delay generic approval and not to advance any clinically important purpose.

2. Brand companies abuse Orange Book listings.

50. Although not intended to do so, the FDA statutes and regulations provide incentives for brand manufacturers to list any and all patents in the Orange Book.

51. Any patent listed in the Orange Book can provide a guise for a patent infringement suit. The mere filing of a suit can substantially delay any generic from coming to market even if the relevant patents (1) do not cover the drug; (2) are not the type of patents that could be asserted in a patent infringement action; or (3) cannot be expected to hold up to judicial scrutiny.

3. Brand companies file and prosecute meritless patent litigation.

52. Although not intended to do so, the FDA statutes and regulations provide incentives for brand manufacturers to sue any generic competitor that files an ANDA with a Paragraph IV certification, even if the brand manufacturer's patents are invalid or unenforceable, or the ANDA applicant's product does not infringe the listed patents.

53. Filing *any* infringement suit delays final FDA approval of an ANDA for up to 30 months (and possibly longer), regardless of the merits (or lack thereof) in the claims. As the FDA recognizes, "[t]he process of patent certification, notice to the NDA holder and patent owner, a 45-day waiting period, possible patent infringement litigation and the statutory 30-month stay mean there is the possibility of a considerable delay in the approval of ANDAs as a result of new patent listings."

4. Brand companies file frivolous FDA petitions.

54. Although not intended to do so, the FDA statutes, regulations, and practice provide incentives for brand manufacturers to file baseless citizen petitions – particularly prior to a legislative change in 2007.[24]

55. The citizen petition process has been commonly used by brand name pharmaceutical manufacturers as a tactic to extend their monopolies on brand name drugs. Specifically, because the FDA delays final approval of a pending ANDA - sometimes for

[24] In the fall of 2007, Congress changed the law to curb abuse of petitions to the FDA. Prior to the change in law the petition process could be routinely delayed by the FDA's need to pass on the petition in a comprehensive manner prior to ANDA approval. The FDA Amendments Act empowered FDA to summarily deny petitions whose primary purpose, in FDA's assessment, is to delay generic entry. The Act was introduced on June 28, 2007, passed by the House of Representatives on September 19, 2007, passed by the Senate on September 20, 2007, and became effective on September 27, 2007. *See* 21 U.S.C. § 355(q); 110 P.L. 85; 2007 H.R. 2009.

substantial periods of time - while it evaluates citizen petitions, brand manufacturers have routinely submitted citizen petitions to the FDA that do not raise legitimate concerns about the safety or efficacy of generic products in an attempt to preserve their monopolies past the end of their patents' legitimate exclusivity periods. These kinds of citizen petitions do not raise legitimate concerns about the safety or efficacy of generic products, but instead seek to preserve monopolies after the end of exclusivity period(s).

56. The cost of filing sham citizen petitions is trivial compared to the value of securing an additional period of monopoly profits.

57. All of this is common knowledge in the pharmaceutical industry.

58. FDA officials have acknowledged ongoing abuses of the citizen petition process. Former FDA Chief Counsel Sheldon Bradshaw noted that in his time at the agency, he had "seen several examples of Citizen Petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."

59. In July 2006, Gary Buehler, Director of the FDA's Office of Generic Drugs, Center for Drug Evaluation and Research ("CDER"), testifying before Congress on abuses of the citizen petition process by brand name pharmaceutical companies, stated that of forty-two citizen petitions raising issues about the approvability of generic products, "very few . . . have presented data or analysis that significantly altered FDA's policies." Of these forty-two petitions, only three led to a change in the FDA's policy on the basis of data or information submitted in the citizen petition.

60. Other federal agencies have also recognized the ongoing abuse of the citizen petition process by brand manufacturers. FTC Chairman Joe Leibowitz lamented that the citizen petition process is "susceptible to systematic abuse", and that "[i]t is no coincidence that brand companies often file these petitions at the eleventh hour before generic entry and that the vast majority of citizen petitions are denied."

61. In recent years, only about seven percent of citizen petitions regarding the approvability of generic products led to any change in the FDA's policy on the basis of data or information submitted in the petition.

5. Brand and generic companies enter into anticompetitive settlement agreements.

62. Although not intended to do so, the FDA statutes and regulations provide incentives for brand manufacturers to "settle" infringement suits by paying the first filed generic to stay off the market, thus (i) withdrawing that competitive threat from the market, and (ii) "bottlenecking" approval for other would-be generic competitors. A drug patent settlement in which the brand company pays the generic company to drop a patent challenge has anticompetitive effects, including delayed generic competition and articifial life extension for invalid patents. Because the first filed generic is entitled to six months of market exclusivity (as to other generics), some agreements push off the entry date of the first generic filer, which can block all other generics from coming to market for at least as long as the market exclusivity period lasts. The brand benefits by holding on to its monopoly for longer and the generic benefits from the compensation while still retaining its own period of exclusivity. But purchasers suffer by not having access to more affordable generic drugs.

63. Although not intended to do so, the FDA statutes and regulations provide incentives for parties to delay or avoid the formal settlement of their patent infringement litigation. Since the FDA is prohibited from approving a generic until the earlier of thirty months or a court decision on infringement and invalidity, both parties have an incentive to resolve the dispute on anticompetitive terms without formally settling or dismissing the litigation. As long as the suit remains "open," and without a decision on the merits, the FDA cannot approve the generic and the patents remain presumptively valid, allowing the patent holder to continue anticompetitive patent enforcement against other follow-up ANDA filers. Thus, the "open" lawsuit and artificially engineered delay in FDA generic approval can mask anticompetitive collusion.

V. FACTS

A. From 1962 to the late 1990s: Elan and its predecessor companies sell and consumers safely use metaxalone for decades.

64. In 1962, the FDA approved the marketing and sale of metaxalone as a 400 mg pill to be taken in 800 mg increments (*i.e.*, two tablets) three to four times per day for the relief of discomfort associated with acute musculoskeletal conditions. (The FDA approved Elan's application to market and sell metaxalone as an 800 mg pill on August 30, 2002.) Marketed under the brand name Skelaxin, metaxalone was sold continuously in the United States without generic competition for almost five decades. Elan acquired and marketed Skelaxin from 1998 to June 2003.

65. As part of the agency's Drug Efficacy Study Implementation, the FDA evaluated a report received from the National Academy of Sciences National Research Council pertaining to the efficacy of Skelaxin and concluded, in a 1970 *Federal Register* notice, that there was a

lack of substantial evidence that Skelaxin was effective. The FDA gave interested parties the opportunity to submit any pertinent data from adequate and well-controlled studies regarding the efficacy of the product.

66. Two years later, in a 1972 *Federal Register* notice the FDA gave interested parties the opportunity to request a hearing regarding the Agency's proposal to withdraw approval of the NDA for Skelaxin. In 1974, following the presentation of evidence of Skelaxin's effectiveness, the FDA found Skelaxin effective for the relief of discomfort associated with acute painful musculoskeletal conditions.

67. Skelaxin's effectiveness was established without pharmacokinetic assessments and clinical data showing the relationship between dose and exposure and safety and effectiveness of the drug. Nor did the evidence of Skelaxin's effectiveness clearly identify Skelaxin's mode of action. Metaxalone does not directly relax tense skeletal muscles in man. Because Skelaxin does have a sedative effect, many surmise that the sedative effect explains the reports of effectiveness.

68. Skelaxin contains an active pharmaceutical ingredient different from those found in other muscle relaxants, and it has a mechanism of action that is distinct from other muscle relaxants. Skelaxin has a unique pharmacokinetic and safety profile. It is fast-acting, does not interfere with the motor activity used to maintain posture and balance, does not produce a loss of muscle tone, has a low incidence of side effects and drowsiness, and exerts no adverse cardiovascular effects.

69. The patent on the metaxalone compound, U.S. Patent No. 3,062,827 (the "'827 Patent"), was issued in November 1962 and expired in or about 1979.

70. The FDA-approved Skelaxin label has not included an instruction as to whether patients should take Skelaxin with or without food. However, over its decades of use, metaxalone was repeatedly described in the public literature as being taken with food. For example, Micromedex, a resource commonly used by many physicians, disclosed that a number of muscle relaxants, including metaxalone, "may be crushed and mixed with a little food or liquid if needed to make the tablets easier to swallow." Other articles appearing in widely distributed medical literature described metaxalone as a medication "to be taken with food", or given "with milk or food", or "after each meal", or "after meals." And since metaxalone was to be consumed about four times a day, inevitably it was being taken with food.

71. In sum, metaxalone has been used for decades, with millions of annual prescriptions, without significant toxicities and with a scarcity of reported adverse events. There is no demonstrated, clinical dose response for either effectiveness or safety. It is commonly taken with food.

B. Late 1990s to mid-2003: Elan sets the groundwork for later generic delay efforts, and Mutual makes early efforts to develop generic metaxalone.

72. From the late 1990s until mid-2003, Elan undertook a series of actions to lay the groundwork for generic metaxalone delay strategies. Although Elan is not named as a defendant in this case, Defendant King purchased the Skelaxin brand from Elan, and King continued Elan's strategies to delay generic entry of metaxalone for its own benefit.

1. Mutual meets difficulty in its early metaxalone formulations and works to slow down entrance by other potential generic competitors in 2001.

73. By the late 1990s, would-be generic competitors for Skelaxin had begun formulating potential bioequivalent metaxalone products. Mutual was one such competitor.

74. Beginning around 1998, Mutual collaborated with SigmaPharm, Inc. ("SigmaPharm"), a Delaware corporation engaged in the business of the development of pharmaceutical technologies and products. Under Mutual's agreement with SigmaPharm, SigmaPharm's President, Dr. Spireas, assumed responsibility for Mutual's laboratory and research activities related to obtaining FDA approval for generic metaxalone.

75. By 2000, Mutual claimed to have developed two formulations of generic metaxalone. Each formulation satisfied *in vitro* bioequivalence testing, *i.e.*, each formulation displayed bioavailability characteristics sufficiently similar to Skelaxin to satisfy FDA standards when tested outside of a living organism in dissolution tests. *In vitro* testing is commonly accepted for FDA bioequivalence bioavailability testing, but Skelaxin's significant insolubility presented slow dissolution characteristics, so Mutual also undertook *in vivo* testing. However, Mutual's formulations were not bioequivalent to Skelaxin when tested *in vivo*, *i.e.*, when tested in human participants in a fasted state.

76. While Mutual was unable, at that point, to develop its own bioequivalent metaxalone product, it wanted to make sure that other would-be generic manufacturers would not beat it to the punch. In early 2001, representatives of Mutual approached Elan (its would-be brand competitor) in an effort to collaborate with Elan on extending Elan's Skelaxin monopoly. Mutual informed Elan that if the FDA imposed a requirement on ANDA applicants to submit *in vivo* bioequivalence studies, such a requirement "would effectively give Elan another year of exclusivity on the [Skelaxin] product." And in March of 2001, Mutual submitted a petition to the FDA requesting the FDA withhold ANDA approval for generic metaxalone unless the applicant could demonstrate bioequivalence through fasting conditions based on *in vivo* testing.

2. Elan begins generic delay strategies for metaxalone in 2001.

77. By the early 2000s, Elan had become aware that several generic companies were developing generic metaxalone. In 2001, Elan created a so-called "life cycle management" ("LCM") team. One of the key objectives of the LCM team was "delaying generic entry." A senior Elan executive, acknowledging that this exclusionary objective was accurately characterized, noted that "[w]e can think it, say it, but not write it," as that description was "legally unacceptable."

78. A first order of business for Elan's Skelaxin "life extension" plan was to join Mutual in requesting that the FDA reject metaxalone ANDAs that used only *in vitro* bioequivalence testing, and require metaxalone ANDAs to present *in vivo* bioequivalence testing.

79. In February of 2001 and again April of 2001, Elan wrote the FDA's Office of Generic Drugs and presented it with data showing metaxalone to be a low solubility product, inappropriate for waiver of *in vivo* testing. Elan also joined Mutual's argument that metaxalone is too insoluble to permit *in vitro* dissolution studies to be predictive of *in vivo* bioavailability.

80. In 2001, Elan commissioned studies of whether the ingestion of food has an effect on measured metaxalone bioavailability. During that year, Elan conducted a crossover study in forty-two healthy volunteers given a single dose of Skelaxin in a fed and fasted state. Of course, the study was designed to find a statistical difference between fed and fasted bioavailability. The fasted participants had not eaten during a 10-hour overnight fast. Fed participants in the study were given fifteen minutes to eat a high fat breakfast consisting of two eggs fried in butter, two strips of bacon, two slices of toast with butter, four ounces of hash brown potatoes, and one glass of whole milk. Participants were then administered a single dose (400 mg) of metaxalone.

81. According to Elan, the study showed that fed participants experienced a statistically significant higher rate (known as Cmax) and extent (known as AUC) of absorption than those in a fasted state.

82. It is important to know what these results meant, and what they did not mean. *Bioavailability* refers to the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug product and becomes available at the site of drug action. *Bioequivalence* studies test the rate and extent of absorption of the test drug to determine whether the test drug shows a significant difference from the rate and extent of absorption of the reference drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses. Both types of studies are designed to measure how quickly the active ingredient is released from the formulation, enters the blood stream, and reaches a certain level in the blood, and whether the presence or absence of food impacts the ability of the drug to get into the blood stream at the appropriate rate and level. The studies are used by the FDA to review ANDAs to make the comparison required by law–the comparison between a proposed generic product and the reference (*i.e.*, brand) drug.

83. Bioavailability and bioequivalence studies are not designed to demonstrate, and do not show, clinical therapeutic results (the safety or effectiveness) of the tested drug.

84. Elan's food effects studies were a form of bioavailability testing. They demonstrated a differing rate and extent of measured absorption in the body. They might be useful in the FDA determining whether *in vivo* bioequivalence testing for ANDAs might be required in both fed and fasted participants.

85. But the studies were not designed to test, and did not show, any clinically significant differences in therapeutic effect (safety or effectiveness) of taking Skelaxin with or

without food. First, although the bioavailability studies comparing individuals taking Skelaxin in fed and fasting conditions revealed different drug absorption levels, the studies did not identify any relationship between the absorption levels and safety or efficacy. The studies thus contained no evidence that safety decreases or efficacy increases depending on absorption. Second, the tests themselves bore little or no relationship to the conditions under which most individuals use Skelaxin. In the fed state, the participants were given a very high fat meal, but most individuals do not regularly eat high fat meals, and the increased rate and extent of absorption of Skelaxin will be considerably less for patients who consume diets of modest amounts of fat. Therefore, a typical patient's absorption levels would not be significantly affected by whether he or she takes Skelaxin on an empty stomach or with food. Third, Skelaxin is dosed for repeated administration, *i.e.*, 800 mg three or four times a day. The study, in contrast, measured absorption after a single episode of taking one 400 mg dose. The study was thus not designed to measure the conditions of steady state usage at the 800 mg level.

86. While Elan was finishing these food effect studies, the heat turned up on the potential for generic entry. On or about August 31, 2001, generic company Eon Labs, Inc. ("Eon") sought FDA approval to market a 400 mg version of generic metaxalone in the United States. Elan knew that the FDA would be reviewing the Eon ANDA; if it wished to put roadblocks in the way, it needed to act.

87. In October 2001, Elan sent a petition to the FDA asking the FDA to impose both fed *and* fasted *in vivo* bioequivalence testing on ANDAs for generic metaxalone. Elan included the results of the food effects study.

88. Several months later, in January and March of 2002, the FDA issued decisions on the respective requests of Mutual and Elan to impose in vivo bioequivalence testing on ANDAs

for generic metaxalone. The FDA agreed to require an ANDA for generic metaxalone to include acceptable fed and fasted state bioequivalence studies comparing the generic product to Skelaxin because the FDA recognized that: (1) metaxalone is a low solubility product for which dissolution testing may not be reflective of *in vivo* performance; (2) Mutual's data showed its *in vitro* tests were not predictive of *in vivo* performance, and (3) fed and fasted states might result in different bioavailability measurements. The FDA said nothing about whether there was any clinical significance to this testing, and it did not require any change to the Skelaxin label regarding dosing or instructions as to whether the drug should be taken with or without food.

3. Elan seeks patents from the PTO for an "invention" regarding food effects on metaxalone bioavailability in 2001.

89. When Elan sent its October 2001 submission to the FDA, it could have left well enough alone. It (as well as Mutual) had made submissions to the FDA seeking heightened *in vivo* testing requirements for metaxalone ANDA applicants, and these applications were backed with data of a type the FDA might possibly accept (*i.e.*, they were relevant for how to test bioequivalence between proposed generic and reference listed products). And if accepted, the new requirements might considerably delay would-be generic makers for legitimate reasons.

90. But this was not enough for Elan. Elan viewed the use of its Skelaxin bioavailability studies not as a legitimate tool for regulatory use, but as "another grenade to throw in front of generic companies." Elan chose a one-two strategy of generic blocking: first, it would change the FDA approved Skelaxin label to report the results of its food effect studies, and second, it would patent the food effect "phenomenon." If successful, any would-be generic maker would need to include the food effect data on the FDA approved label for its product

(generic labels in general need to be the same as the brand label), and by doing so the generic product would infringe Elan's patent on the food effect phenomenon.

91. And so Elan proceeded with its blocking strategy. On October 16, 2001 (and after submitting its petition to the FDA regarding ANDA *in vivo* bioequivalence testing), Elan filed a supplement to its Skelaxin new drug application. The supplement sought to revise the pharmacokinetics section of the then-current label to reflect the results of the pharmacokinetic food effect study.

92. And in December of 2001, Elan filed an application with the United States Patent and Trademark Office ("PTO") seeking to patent claims relating to the food effect on metaxalone bioavailability. The claims (variously phrased, and somewhat changed during prosecution of the patent) combined (i) the notion that measured bioavailability of metaxalone increases with (ii) metaxalone being taken with food.

93. From the outset, any reasonable practitioner would know that claims allowed under this application would not be able to withstand later scrutiny in the courts. A claim is "allowed" if it complies with the provisions of 35 U.S.C. § 1, *et seq*. Two immutable obstacles stood in the way to validity of any allowed claims.

94. First, there was nothing novel about taking metaxalone with food. Metaxalone had been in use in the United States for forty years. The literature repeatedly described its use with food. Its multiple (three to four times a day) dosing meant that it was constantly being taken in a non-fasted state. Allowed claims for taking metaxalone with food would be ruled invalid.

95. Second, a basic tenet of patent law is that one cannot patent a phenomenon of nature. In 2001, any objective patentee would know that a patent on a natural phenomenon or

the dissemination of information about that natural phenomena, would not stand up to a validity challenge. To obtain a valid patent related to a phenomenon of nature, one would need to invent a new application of that phenomenon to a novel and useful end. For example, if one were to discover that, as a result of the increased bioavailability of metaxalone when taken with food, one could effectively treat dementia in humans, one could patent a method of using metaxalone when taken with food to treat that condition. But the "discovery" that there is an increase in bioavailability when Skelaxin is taken with food is nothing more than a "discovery" of a natural phenomenon. Just because something is "discovered" and communicated to people, does not make it patentable. As the Supreme Court has stated in summing up decades of settled patent jurisprudence: "Einstein could not patent his celebrated law that E=mc2; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'"[25] Allowed claims for the phenomenon that bioavailability measurements of metaxalone increase with food would be held invalid.

96. Despite the fact that Elan would lose an infringement case based on claims to the phenomenon of increased measurements of rate and extent of metaxalone absorption when taken with food (if pressed to a ruling on the merits), Elan persisted with its strategy. This decision made economic sense. The costs of obtaining the patent (and later listing and prosecuting meritless litigation over it) were far outweighed by the huge financial return to Elan from delayed generic entry. And while its acts of delaying generic entry would be unlawful, the financial return would likely far surpass any eventual reckoning for its transgressions.

[25] *Mayo Collaborative Services v. Prometheus Labs.*, 132 S. Ct. 1289, 1293 (Mar. 20, 2012) (citations omitted).

4. CorePharma files an ANDA for 400 mg generic metaxalone in April 2002.

97. In April 2002, CorePharma filed an ANDA with the FDA, seeking approval to market and sell generic metaxalone in 400 mg tablets. CorePharma proposed labeling for its generic consistent with Skelaxin's then-existing label.

5. In mid-2002, the FDA rules that Elan may include data from the food effect bioavailability study on the Skelaxin label.

98. The FDA approved Elan's sNDA in May 2002 and issued a superseding approval letter on June 20, 2002. The May and June approvals allowed Elan to add a pharmacokinetics section to Skelaxin's label and include information from a single food effect bioavailability study it commissioned involving forty-two volunteers and a single 400 mg dose of Skelaxin. The new language declared "following a standardized high fat meal, food statistically significantly increased the rate . . . and extent of absorption . . . of metaxalone . . . ."

99. The food effect bioavailability study Elan submitted demonstrated no clinical effect arising from fed- and non-fed-state bioavailability. As a result, the FDA did not deem the inclusion of information from the study to be necessary for the safe and effective use of metaxalone. The study also resulted in no new information about dosing or administration and no changes to the warnings, precautions, or contraindications sections of the label.

100. The FDA initially, on May 31, 2002, approved an addition to the label stating "[g]iven the magnitude of the plasma level changes following a high fat meal, Skelaxin tablets should be administered on an empty stomach." Displeased with this, Elan lobbied the FDA, pointing out that its study did not show clinical effect and that there was no known correlation between enhanced drug concentrations and increased adverse events. On June 20, 2002, the FDA relented and instructed Elan to remove the language regarding dosing on an empty stomach and instead state that "the clinical relevance of [the food] effects is unknown." Elan had now

planted the food effects bioavailability information on the label; the first step of the strategy was in place.

6. In June 2002, the Patent and Trademark Office issues the ’128 Patent to Elan.

101. In June 2002, Elan’s plan to patent the food effect phenomenon succeeded, and the PTO issued patent number 6,407,128 (the “’128 Patent”). This new patent issued over twenty years after the expiration of the original ’827 Patent on the metaxalone compound. Elan obtained an assignment of the ’128 Patent from two of its employees, Michael Scaife and Jaymin Shah. And shortly thereafter, Elan listed the ’128 Patent in the Orange Book as covering Skelaxin, with an expiration date of December 3, 2021. The second step of its strategy was in place.

102. Elan knowingly listed the ’128 Patent, an ineligible patent, in the Orange Book. Elan deliberately and knowingly misused the FDA’s Orange Book listing process with respect to the ’128 Patent in an effort to exclude AB-rated generic competition to Skelaxin.

7. In August 2002, Elan gains approval for an 800 mg version of Skelaxin.

103. Meanwhile, Elan had also taken steps to prepare to shift the metaxalone market from 400 mg to 800 mg tablets. On August 30, 2002, the FDA granted Elan’s supplemental NDA seeking approval to market and sell an 800 mg version of Skelaxin. Until then, Skelaxin had only been approved as a 400 mg pill, although the prescribed dosage is typically 800 mg to be taken three to four times per day (for a total of 2400 or 3200 mg).

104. As a result of Elan’s shift from 400 mg to 800 mg tablets, would-be generic makers must shift from 400 mg development efforts to 800 mg efforts if they wished the benefits of automatic substitution. To pursue 800 mg tablets, Eon (the would-be generic then first to file

with an ANDA for a 400 mg generic metaxalone) would need to re-formulate and file (or amend) and ANDA for 800 mg, and other would-be generics would need to do the same.

8. In January 2003, following the first ANDA filing for metaxalone, Elan files baseless infringement litigation against Eon.

105. On November 7, 2002, after learning of issuance of the ’128 Patent, would-be generic maker Eon sent a Paragraph IV notice to Elan indicating that (i) its 400 mg generic metaxalone product would not infringe the ’128 Patent, and (ii) the ’128 Patent was invalid. Eon explained (as any reasonable practitioner would) that the claims were precluded both because (i) the notion of taking metaxalone with food was long known by physicians and others, and (ii) the notion that the oral bioavailability of metaxalone to a patient increases when metaxalone is taken with food is simply a “characteristic . . . inherent to the method.”

106. Because Eon was the first ANDA applicant for 400 mg generic metaxalone (and the first to file a Paragraph IV certification to overcome the ’128 Patent), Eon was the “first to file” generic maker for 400 mg metaxalone. Eon would be entitled to 180 days of marketing exclusivity for the 400 mg product once it could obtain final FDA approval of its 400 mg metaxalone ANDA.

107. On January 2, 2003 – and despite knowing that it would eventually lose the litigation if fought to the finish – Elan brought suit against Eon for infringement of the ‘128 Patent in federal district court for the Eastern District of New York (the “Eon ’128 litigation”). By filing this suit, Elan triggered an automatic period of 30 months during which the FDA could not approve Eon’s ANDA for 400 mg metaxalone.

108. The Eon ’128 litigation was a sham. No reasonable practitioner would conclude the patentee to have a realistic likelihood of prevailing on the merits. Each of the patents in this

case (some later described) that King listed and continued to maintain in the Orange Book with respect to Skelaxin would be known by any reasonable practitioner to be invalid as inherently anticipated and/or obvious in light of the prior art. Each is of the same character – they disclose an existing property of Skelaxin and covered methods of administering the product in a manner consistent with that inherent property – and "informing" patients or providers of the information did not make the claims any more patentable. No reasonable litigant could have believed, in light of the existing state of the art, that any of those patents would survive judicial scrutiny. No litigant would reasonably believe those patents to be valid or to permit a reasonable claim of patent infringement to be asserted.

9. In March of 2003, Elan files baseless infringement litigation against CorePharma, the second ANDA filer for metaxalone.

109. On or about January 24, 2003, CorePharma amended its April 2002 ANDA for 400 mg generic metaxalone and served Elan with a Paragraph IV certification concerning the '128 Patent. The '128 Patent issued in June 2002, after CorePharma's initial filing. In February 2003, CorePharma petitioned the FDA to allow it to waive the requirement of a Paragraph IV certification for its metaxalone ANDA and instead submit a Section VIII statement, noting that the ANDA sought approval for the same indication and conditions for which metaxalone had long been approved and did not seek approval for the method of use covered by the '128 Patent. If granted, CorePharma's Section VIII statement would carve out of the generic label the food effect information ostensibly covered by the '128 Patent.

110. In response, on or about March 7, 2003, Elan commenced litigation against CorePharma in the United States District Court for the District of New Jersey alleging infringement of the '128 Patent. Once again, under Hatch-Waxman this lawsuit resulted in an

automatic, thirty-month stay of approval of CorePharma's ANDA. The case was transferred to the United States District Court for the Eastern District of New York in June 2003 (the "CorePharma '128 litigation").

111. The CorePharma '128 litigation suffered the same terminal problems as the Eon matter. It too was a sham. No reasonable practitioner would conclude the patentee to have a realistic likelihood of prevailing on the merits

10. In March of 2003, Mutual becomes the third generic manufacturer to file an ANDA for 400 mg generic metaxalone but does not include a Paragraph IV certification.

112. In or about March 2003, would-be generic maker Mutual filed an ANDA for 400 mg generic metaxalone. Unlike the prior two ANDAs (by Eon and CorePharma) Mutual chose not to file a Paragraph IV certification, but instead certified under Section VIII that the '128 Patent did not claim a use for which Mutual was seeking approval. Mutual requested that the FDA "carve out" the allegedly infringing method of use (i.e., the food effect bioavailability data) from the label for Mutual's generic metaxalone.

C. Mid-2003 to late 2005: King engages in generic delay efforts.

113. By mid-2003, Elan's Skelaxin brand reported United States sales of approximately $145 million per year. While Skelaxin had no generic competition at the time, at least three would-be generic makers – Eon, CorePharma, and Mutual – had filed ANDAs seeking metaxalone generic approvals. Elan had procured the '128 Patent and had commenced infringement actions against two of the generics in the Eon '128 and CorePharma '128 litigations. While Elan would lose these cases (if pressed to a final merits ruling), the purpose of the suits was already being fulfilled – the 30 month automatic stay would delay generic entry and the *in terrorem* effect (even for these frivolous lawsuits) might further dissuade a later, at-risk

launch. Elan also had obtained permission, via its sNDA, to amend the pharmacokinetics section of the Skelaxin label to include the data from the food effect study. The groundwork for later generic delay strategies was in place.

114. King now took over Skelaxin and pursued an anticompetitive scheme to unlawfully exclude generic competition for Skelaxin. This scheme included: (1) initiating and continuing baseless litigation against putative generic competitors Eon (later purchased by Sandoz), Mutual, and CorePharma based upon patents that any reasonable practitioner knew would be held invalid; (2) filing baseless citizen petitions; and (3) entering into the King-Mutual conspiracy, whereby Mutual agreed not to come to market with a generic metaxalone product, King and Mutual engaged in a joint campaign of filing sham citizen petitions with the FDA in order to obstruct and delay FDA approval for other, would-be generic competitors, and cooperated in baseless litigation against Eon/Sandoz.

1. In April 2003, Elan sought a label change to add more food effects information.

115. On April 23, 2003, Elan submitted an sNDA to revise Skelaxin's label to incorporate the results of two studies conducted to determine the effects of age and gender on the bioavailability of Skelaxin. The studies purported to show that bioavailability increases with age in the fasted state and is higher in women than in men in both the fasted and fed states. The studies did not, however, demonstrate any clinical safety or efficacy effects. Elan concluded age-related variations in the bioavailability of Skelaxin are minimized when Skelaxin is administered with food and sought label language to reflect that conclusion.

2. In June 2003, CorePharma receives tentative approval for 400 mg metaxalone.

116. The FDA tentatively approved CorePharma's ANDA for 400 mg generic metaxalone in June 2003. But the FDA could not grant final approval to CorePharma until at least October 2005 given the automatic thirty-month stay triggered by Elan's March 2003 filing of the CorePharma '128 litigation.

3. In June 2003, King acquires the rights to Skelaxin and takes over Elan's unlawful generic delay efforts.

117. In or about June of 2003, Elan sold all its rights in Skelaxin to defendant King. In the transaction, King acquired Skelaxin and another drug from Elan for approximately $750 million. In connection with its purchase of the rights to Skelaxin, a transaction originally valued at over $850 million, King conducted extensive due diligence into the value of the drug, including an investigation into intellectual property rights, marketing plans, development plans, sales projections, and any threats to its value, such as the pending and anticipated patent litigation.

118. From June 2003 forward, King controlled the marketing and intellectual property for Skelaxin. Also as part of its sale, Elan licensed to King the '128 Patent and its rights to the patent application that gave rise to the '102 Patent (follow-on claims were still being prosecuted). Within four years, King would grow Skelaxin sales to exceed more than $440 million in the United States annually.

119. As part of the purchase of the Skelaxin franchise, King took over for Elan in the Eon '128 and CorePharma '128 litigations. Based upon the due diligence that it conducted in connection with its purchase of the Skelaxin franchise, King knew that it had no reasonable chance to prevail on the merits of either of the pending patent lawsuits -- the '128 Patent was

inherently anticipated and/or obvious over numerous pieces of prior art. As James Green, former Executive Vice President of Corporate Affairs for King, has conceded: "[T]here was a concern about [generic entry] from the time [King] acquired [Skelaxin from Elan]."

120. In conducting its due diligence prior to buying the Skelaxin franchise from Elan, King analyzed the '128 Patent and knew that it should not have been listed in the Orange Book. Upon taking over the Skelaxin franchise, King knowingly continued to maintain the improper Orange Book listing of the '128 Patent. Thus, King deliberately and knowingly misused the FDA's Orange Book listing process with respect to the '128 Patent in an effort to exclude AB-rated generic competition to Skelaxin.

121. Indeed, from and after June 2003, King took control all aspects of Elan's prior activities used to block entry of a generic metaxalone product. King took over the Eon '128 litigation, which it knew was a sham. King took over the CorePharma '128 litigation, also a sham. King took up the cause of Elan's sNDA, seeking to force would-be generic makers to include clinically inconsequential information about the food effect on metaxalone bioavailability on their approved labels for generic metaxalone. King took up Elan's further prosecution of patent claims under the application from which the '128 Patent issued. And King took up the right to bring the next frivolous '128 Patent suit, this one against Mutual.

122. King could have stopped each of these things. It could have dismissed the frivolous Eon '128 and CorePharma '128 litigations. It could forbear from fighting generic carve-outs of the food effect data. It could have told its patent lawyers to desist from further efforts to procure patents relating to a natural phenomenon which it knew would not hold up in court. But King did not stop; it pressed even harder, for years, to block generic entry.

4. In January 2004, King procures the invalid ’102 Patent.

123. From mid-2003 until early January 2004, King assumed prosecution of claims under the same patent application from which the ’128 Patent had issued. In January 2004, the PTO issued patent number 6,683,102 (the “’102 Patent”).

124. The ’102 Patent was “directed to methods of providing metaxalone to patients while informing them that taking metaxalone with food results in higher blood levels of metaxalone.” The claims (variously phrased and somewhat changed during prosecution of the patent) combined: (i) the notion that measured bioavailability of metaxalone increases when metaxalone is taken with food; and (ii) informing someone about the increased bioavailability of metaxalone when taken with food. The “new” aspect of the ’102 Patent was the “informing” part.

125. The ’102 Patent suffered the same frailties as the ’128 patent: the claims in the ’102 Patent were invalid for anticipation by the prior art and for obviousness.

126. First, the prior art contained repeated references to the administration of metaxalone with food or a meal. These prior art references disclosed the “invention” of taking metaxalone with food, rendering the claim invalid for anticipation.

127. Second, for over 40 years it had been known to give metaxalone with food. Newly discovered results of known processes are not patentable because such results are inherent. Thus, a naturally occurring side effect of administering metaxalone with food – that it results in increased bioavailability – does not create entitlement to a valid patent.

128. The “informing” part did nothing to improve the fatally weak patent protection. Because the food effect is an inherent property of the prior art and, therefore, unpatentable, informing a patient of that inherent property is also unpatentable. Moreover, a valid patent may

not be based solely on the dissemination of information. Allowing a patentee to exclude others from informing people of scientific discoveries is anathema to the aims of the patent statute, which favors disclosure.

129. In early 2004, King listed the '102 Patent in the Orange Book as covering Skelaxin with an expiration date of December 3, 2021.

130. King knowingly listed the '102 Patent, an ineligible patent, in the Orange Book. King deliberately and knowingly misused the FDA's Orange Book listing process with respect to the '102 Patent in an effort to exclude AB-rated generic competition to Skelaxin.

5. In March 2004, King commences baseless litigation against would-be generic maker Mutual.

131. On January 29, 2004 and in light of King's listing the '102 Patent, Mutual sent King a letter notifying it of Mutual's filing of a Paragraph IV certification claiming that the '102 Patent "is invalid, unenforceable or will not be infringed by Mutual's metaxalone tablets (400 mg)." Mutual detailed the basis for non-infringement – that nothing Mutual would be doing would be "informing" patients of the Skelaxin food effect data. Mutual concluded with forceful remarks:

> [The] institution of baseless litigation against an applicant seeking approval to market a generic drug product can give rise to antitrust liability. The Federal Trade Commission . . . has strongly condemned such tactics. . . . Suffice it to say, should King [or its subsidiary] choose the precarious route of filing suit against Mutual, it is reasonably certain that the FTC will have a great interest in such litigation.

132. By being the first company to file a Paragraph IV certification as to the '102 Patent, Mutual could expect to share exclusivity with Eon on 400 mg generic metaxalone. Eon and CorePharma subsequently made Paragraph IV certifications against the '102 Patent in connection with their respective ANDAs for 400 mg generic metaxalone.

133. On or about March 12, 2004, King commenced litigation against Mutual in the United States District Court for the Eastern District of Pennsylvania in response to Mutual's Paragraph IV filing as to the '102 Patent (the "Mutual '102 litigation"). As with other suits, this lawsuit resulted in an automatic thirty-month stay of approval of Mutual's ANDA.

134. The Mutual '102 litigation was a sham, at least for the same reasons that the Eon '128 and CorePharma '128 litigations were baseless. No reasonable practitioner would conclude the patentee to have a realistic likelihood of prevailing on the merits.

6. In March 2004, the FDA concludes food effect bioavailability data need not appear in generic metaxalone labels.

135. During late 2003 and early 2004, the FDA brought considerable attention to the issue of whether generic makers of metaxalone could "carve out" from the approved label the food effect pharmacokinetic data, the subject of the '128 Patent. In February 2003, CorePharma had requested that the FDA allow it to file Section VIII statement regarding the '128 Patent and carve out of its generic label the food effect data King contended was patent protected. Since the data completely lacked any clinical therapeutic significance (for either safety or effectiveness), a compelling case had been made to the FDA that while King could be *allowed* to include the clinically inconsequential data on its label, generics ought *not be required* to carry it on the generic label.

136. On March 1, 2004, in a letter from the Director of the Office of Generic Drugs, the FDA announced that it had determined that "omission of information regarding fed-state bioavailability [from the labeling] will not negatively affect the safe use of metaxalone." Given this, ANDA applicants for generic metaxalone could carve out, pursuant to Section VIII, the use listed in the Orange Book that related to the '128 Patent. The FDA stated that it had received

"information and analysis that has persuaded [it] that the [information protected by the '128 Patent] may be carved out of the metaxalone labeling without rendering the drug less safe or effective for the remaining conditions of use."

137. In the letter, the FDA declared "[t]here [is] no data to support an increase in adverse events related to increased drug concentrations." Further, the agency recognized "metaxalone has a long history of safe use. It has been marketed for decades without dosing adjustment information related to fed-state administration. Few adverse event reports have been entered into the Adverse Event Reporting System."

138. The FDA specifically delineated what would be needed to justify requiring inclusion of King's proposed language: "If Elan had conducted clinical trials to demonstrate a clinical effect arising from the difference in fed- and non-fed state bioavailability, the inclusion of such information in labeling might have been considered necessary for the safe and effective use of metaxalone. No such study has been submitted."

139. Because the FDA's ruling allowed would-be generics to provide Section VIII certifications as to the '128 Patent, the only patent standing in the way of Mutual's generic entry was the '102 Patent, subject of the Mutual '102 litigation. In other words, Mutual could come to market as soon as it received FDA approval and the '102 Patent was declared invalid or the thirty-month stay expired.

7. In March 2004, the FDA deemed King's request for more food effects information on the label "approvable."

140. A few days later, on March 12, 2004, the FDA ruled on King's April 2003 sNDA which sought addition of language recommending Skelaxin be administered with food because of potential age-related variations in bioavailability of Skelaxin. The FDA deemed the changes

"approvable," subject to various format modifications. Over the next two and a half years, King and the FDA would trade letters on the changes, with the FDA granting final approval of the language and label change on November 24, 2006.

8. King wastes no time and persists with baseless petitions to the FDA in March 2004 seeking restrictive labeling for generic metaxalone applicants.

141. King did not take long to punch back. On March 18, 2004 King submitted a petition to the FDA requesting the agency (i) rescind its March 1, 2004 Letter; (ii) require all ANDA applicants for generic metaxalone to submit a Paragraph IV Certification against the '128 Patent; and (iii) prohibit the carve out of the food effect data on generic metaxalone labels (the "King March 2004 petition").

142. King also petitioned the FDA on March 18, 2004 for a stay of action to delay FDA approval of any generic metaxalone product until the FDA had ruled on King's March 2004 petition ("the "King stay petition"). King knew the falsity of this but argued that approval of generic metaxalone with a label that carved out the food effect bioavailability data would render the generics less safe and effective. But King admitted that the food effect bioavailability study it submitted to the FDA and one other "were not intended to investigate, and did not determine, the specific clinical significance of the difference observed between fed and fasting administration of Skelaxin."

143. Both the King March 2004 petition and the King stay petition were baseless. No reasonable pharmaceutical company could realistically expect the FDA to adopt the requests in the King March 2004 petition, nor stay the use by generics of labeling carve outs of the clinically inconsequential food effect data.

144. The FDA is a science-based agency. By statute, it is charged to make decisions on the basis of sound, scientific data that bears on a relevant clinical issue of therapeutic importance. The statute and regulatory scheme for labeling carve outs requires the FDA to act only on the basis of sound science directed to a clinical therapeutic end. The FDA had made this clear as applied to these very specific facts. In its March 1, 2004 decision, the FDA stated that in order to reach a contrary decision it needed to be shown "clinical trials to demonstrate a clinical effect."

145. In stark contrast to this mandate, each of King's March 2004 petitions failed to provide *any* relevant information to require the FDA to reconsider its March 1, 2004 decision. The question was whether there was a demonstrated impact of clinical consequence by reason of different bioavailability measurements associated with the intake, or not, of food. But no such data was provided.

146. The King March 2004 petition simply rehashed the data from the studies that the FDA had already reviewed in reaching its March 1, 2004 decision. Without providing the agency any meaningful data upon which to make a decision, there could be no likely change of regulatory policy.

147. King's requests also lacked common sense. Skelaxin had been successfully sold and safely used in the United States for over forty years without the information that King now said was required for it to be safe and effective.

148. The two petitions were baseless, and no reasonable petitioner could have expected to succeed on them. And absent a stay -- which the FDA had not issued and never did issue – the March 1, 2004 carve out decision remained in effect. The only patent standing in the way of Mutual's generic entry was the '102 Patent that was the subject of the Mutual '102 litigation.

9. From April 2004 through late 2005, King and Mutual (with the support of other generic manufacturers) battle it out in submissions to the FDA over generic metaxalone ANDA requirements.

149. For nearly two years, Mutual vigorously opposed King's petition campaign to the FDA.

150. On or about April 5, 2004, Mutual filed an opposition to the King stay petition, asking the FDA to rescind the March 12, 2004 approvable letter for King's sNDA that would add language to the label recommending Skelaxin be administered with food as a result of two studies on the effects of age and gender on the bioavailability of Skelaxin and stay approval of any new Skelaxin labeling that discusses dosing with food. Mutual told the FDA that the relief it requested was "necessary to assure that FDA does not inadvertently facilitate an anticompetitive scheme by King to prevent generic competition for metaxalone tablet drug products using faulty medical assumptions derived from dubious scientific data." Mutual would "suffer irreparable injury," it stated, because the company "has invested substantial time and resources in developing a lower priced generic alternative to Skelaxin, and overcoming the various hurdles King and Elan have already put in its way." Mutual implored the FDA to avoid a rushed "decision to approve King's pending label supplement [that] will inadvertently nullify Mutual's costly, pro-competitive investments" in developing its generic metaxalone.

151. Mutual noted that "[f]or the past 40+ years, Skelaxin's labeling has not included any specific instructions vis-à-vis dosing with or without food," and that despite tests showing differing bioavailability when taken with food or without food, "to this day, there is no clinically significant evidence to suggest that the safety or effectiveness of Skelaxin is altered based on whether the drug is dosed in a fasting or fed condition."

152. "Nevertheless," Mutual told the FDA, "for the past several years King and Elan Pharmaceuticals Inc. (the previous owner of the Skelaxin NDA) have been pursuing a strategy to leverage dubious patents and a handful of small, clinically inconclusive bioavailability studies into an additional long-term barrier to generic competition." Mutual summarized the state of affairs: "[u]nfortunately for American consumers, the King/Elan scheme has already delayed the availability of lower cost generic metaxalone products for several years, and if [Mutual's] stay [of the April 2003 sNDA] is not granted, FDA approval of King's proposed labeling changes may inappropriately solidify King's stranglehold on the metaxalone market without conferring any medical or economic benefits on American consumers."

153. CorePharma joined the fray with comments submitted to the FDA on April 30, 2004 opposing the King March 2004 petition and the King stay petition. In the comments, CorePharma noted that, after receiving the FDA's March 1, 2004 letter allowing the carving out of the food effect language from the label (the method of use ostensibly protected by the '128 Patent), it had submitted an amendment to its ANDA for generic metaxalone withdrawing its Paragraph IV certification and instead submitting a Section VIII statement regarding the '128 Patent. CorePharma supported the FDA's March 1, 2004 findings as a "scientifically sound safety determination" and alleged "King's arguments to the contrary are scientifically and legally insupportable, and thus fueled by a transparent commercial incentive to forestall competition."

154. On May 13, 2004, King retorted. King defended against Mutual's claim that it was relying on "dubious" bioavailability studies, responding that Mutual had not reviewed King's studies. But King had not provided Mutual (or any other would-be generic competitor) with the studies it was relying on in its sham citizen petition campaign.

155. King reiterated its position that the FDA should reverse its March 1, 2004 decision. But (once again) King did not submit any of the types of studies that the FDA indicated would be required to reverse its decision. King even admitted that the studies it had previously submitted "were not designed to establish the precise clinical impact of the bioavailability differences on particular patient populations."

156. The May 2004 submission by King was a sham. No reasonable petitioner could have expected to succeed on that request. Again, absent a stay – which the FDA had not issued and never did issue – the March 1, 2004 decision remained in effect. The only patent standing in the way of Mutual's generic entry was the '102 Patent that was the subject of the Mutual '102 litigation.

157. On or about May 17, 2004, Mutual requested the FDA require King make public all the studies in support of its position so that they could be properly scrutinized. Mutual argued that King's descriptions of its studies were "wholly inadequate to support any clinical rationale for inclusion of a fed dosing instruction for Skelaxin." There was, after all, the common sense observation as to why labeling regarding fed state bioavailability was not necessary to safeguard patients from Skelaxin: "Skelaxin is widely regarded as a safe drug. As FDA's medical review of Skelaxin in 2002 noted, for the 30 year period between 1970 and 2000, only 52 Skelaxin-related adverse events were reported to the AERS system [FDA's Adverse Events Reporting System], only 18 of those events were serious, and 'many were confounded by concomitant medication, preexisting medical conditions or lack of clinical[ly] detailed information.'"

158. On February 15, 2005, Mutual submitted yet another letter to the FDA opposing the need to food effect data labeling on generic metaxalone labels. Mutual included the affidavit of Dr. Daniel L. Azarnoff, stating:

> There are no data or other information that would support a determination that metaxalone tablets sold with labeling that omits the information about food effects is either less safe or less effective than a product sold with labeling containing such information. In fact, there are no data or information that even suggests that omission of the information on pharmacokinetics would pose a safety or efficacy problem.

159. This observation was consistent with the millions of prescriptions and over forty years of experience with the safety and efficacy of Skelaxin without the inclusion of such information in the label. Dr. Azarnoff further noted that the pharmacokinetic data included in the label is not relevant given that the dosing instructions in the approved label say nothing about whether Skelaxin should be taken with or without a meal.

10. King enlarges baseless litigation against Eon (later purchased by Sandoz) to include claims over the new ANDAs for 800 mg generic metaxalone.

160. On November 4, 2004, Eon filed an amendment to its ANDA for 400 mg generic metaxalone to also seek approval for 800 mg generic metaxalone at the same time. In the amendment, Eon included Paragraph IV certifications that the ’128 and ’102 Patents were invalid or not infringed. (Eon would withdraw its application for 400 mg metaxalone in September 2006 but proceed with efforts to bring the 800 mg version to market.)

161. Eon was the first Paragraph IV filer with respect to 800 mg generic metaxalone, meaning it would be entitled to 180 days of market exclusivity for 800 mg generic metaxalone upon final approval of Eon’s ANDA, a court order declaring the ‘102 and ‘128 Patents invalid, or the expiration of any applicable statutory stay.

162. On December 17, 2004, King commenced litigation against Eon in the United States District Court for the Eastern District of New York in response to Eon’s Paragraph IV filing for the 800 mg generic metaxalone (the “Eon ’102 litigation”); the suit was subsequently consolidated with the already pending Eon ’128 litigation.

163. King's filing resulted in an automatic, thirty month stay of approval of Eon's ANDA for 800 mg generic metaxalone. The addition of charging infringement on the 800 mg tablet did not, in any way, change the merits of King's litigation position. There were none.

164. During 2005, generic maker Sandoz acquired Eon. Thereafter, Sandoz controlled Eon's ANDA for generic metaxalone. References from this point forward regarding actions on behalf of either Sandoz or Eon are simply attributed to "Sandoz."

D. Late 2005 to 2009: King and Mutual conspire and actively delay generic metaxalone.

1. In the fall of 2005, King and Mutual enter an unlawful agreement to secretly end their disputes and conspire to prevent generic competition.

165. In a remarkable turnaround, by the fall of 2005, King and Mutual began discussing the possibility of colluding to jointly prolong generic entry, rather than fighting over how soon it could occur.

166. While this was a remarkable turnaround, Mutual had planned it for a considerable time. Over the years Mutual had witnessed King's success in delaying generic entry – King had conducted clinically inconsequential bioavailability studies, gained a pharmacokinetic label change to report that data, obtained patents that could not withstand later court scrutiny, and filed a series of sham lawsuits. So at some point, Mutual decided to adopt the same game plan as King – work up some clinically inconsequential bioavailability information about metaxalone, patent it, sell it to King, and join King in delaying *other* generic companies.

167. During 2005, Mutual sponsored three metabolism studies to learn inherent aspects of metaxalone. Mutual claimed the studies showed that metaxalone (i) is metabolized by two cytochrome P450 liver enzymes, (ii) inhibits the activity of six sub enzymes, and (iii) induces the activity of another sub enzyme. At most, the studies aided an understanding of metaxalone's

natural metabolic activity. The studies were not clinical studies; they showed no relevance of the metabolic activity on therapeutic effect (safely or effectiveness), nor on drug-to-drug interactions. As a potential generic competitor to King, Mutual would have no business reason to undertake metabolism studies to show the source of differences in fed versus fasted metaxalone bioavailability. The metabolism studies, by definition, would not elucidate any clinically meaningful information. Instead, they would fall into the same irrelevant bucket as King's food effect bioavailability studies.

168. Although the data from the metabolism studies was clinically inconsequential and demonstrated, at best, an inherent feature of a drug that had been safely sold in the United States for over 40 years, Mutual took a page from King and planned its use for generic delay purposes.

169. In October 2005, Dr. Spireas, head of Mutual's research and development activities regarding generic metaxalone (while also serving as SigmaPharm's President), met with King's President and Chief Executive Officer, Brian Markison, and King's Vice President of Business Development, Adriane Sax. At that meeting, Markison disclosed King's efforts to settle the Skelaxin patent litigation with other generic manufacturers. With the automatic thirty-month stays of FDA action regarding ANDAs concerning the '128 Patent coming to an end and the possibility that the FDA could soon approve Eon's and CorePharma's ANDAs for 400 mg metaxalone, Markison indicated that King would make substantial annual payments to those generic manufacturers to settle the patent litigations that were threatening King's monopoly.

170. Within two months, King and Mutual reached a deal. On or about December 6, 2005, King and Mutual executed an agreement (the "King-Mutual Agreement") under which Mutual agreed (i) not to enter the market with any generic metaxalone product, but instead (ii) to aid King in its effort to delay and obstruct other would-be generic competitors from gaining FDA

approval and launching competitive generic products. The conspiracy would span years, and include the further pursuit of baseless petitions to the FDA, the false maintenance of patent litigation between King and Mutual (when in fact no real dispute remained), sham lawsuits based on Mutual's new metabolism data, and efforts to impose unnecessary FDA labeling requirements on other would-be generic competitors.

171. The substantive positions Mutual would begin pushing with the FDA after the King-Mutual Agreement would not have been fathomable, and certainly not in its own self-interest, were it not for the arrangement with King; Mutual would otherwise be seeking earlier generic entry, with less red tape, and sensible, clinically supported approval requirements. But by joining forces with King to delay generic entry, Mutual could forgo revenue from sales of its own product and instead share in King's prolonged monopoly profits.

172. To buy Mutual's allegiance, King agreed to pay Mutual $35 million and at least 10% of Mutual's revenues from Skelaxin. The companies cast these payouts as "licensing fees" to cover up the otherwise nakedly collusive features of their agreement: King was ostensibly licensing Mutual's intellectual property regarding metaxalone (the metabolism study data), including any patents Mutual might seek or obtain for the drug. King's payment to Mutual of $35 million up front and a "royalty" on sales of King's branded Skelaxin were not dependent on Mutual ever securing any patent, however. Rather, Mutual would receive "royalties" of up to 20% on Skelaxin sales if certain other conditions were met. To date, King has made substantial payments to Mutual exceeding $200 million.

173. But make no mistake about it: these payments were a pretext for the true purpose of the King-Mutual Agreement – delaying generic competition. The agreement would prevent a court decision in the pending lawsuit between King and Mutual, thereby avoiding the likely

ruling of the court that King's patents were invalid. It would keep Mutual from entering the market with its generic metaxalone product. And it would secure Mutual's cooperation in keeping other generic competitors off the market.

174. With the King-Mutual Agreement in hand, Mutual's earlier incentives to challenge King's invalid patents and seek early approval of its ANDA vanished. This was the intended result. Mutual would now receive "royalties" for every sale of branded Skelaxin. It would make more money by helping King keep other would-be competitors off the market than it could make by launching its own generic metaxalone. The more sales of Skelaxin King made (and the longer they could keep generic metaxalone off the market), the more money that Mutual would make. So under the agreement, Mutual ceased its efforts to launch generic metaxalone and instead worked with King to delay market entry of *all* generic metaxalone. This is the King-Mutual conspiracy.

2. In December 2005, King and Mutual conspire and work to delay generic competition by flooding the FDA with additional baseless citizen petitions.

175. Mutual and King wasted no time consummating their conspiracy; within hours, Mutual began working in concert with King to flood the FDA with baseless petitions raising issues designed only to continue King's monopoly and delay FDA approval of any ANDAs for generic metaxalone. These filings succeeded in delaying the FDA's ability to review and approve the ANDAs on file for generic metaxalone.

176. On December 8, 2005 – just two days after signing the King-Mutual Agreement – Mutual committed an about-face and withdrew its prior opposition to King's proposed FDA labeling changes. Mutual was now, abruptly, taking the position that the food effect data may pose a clinically meaningful issue and that the FDA ought to reconsider its March 1, 2004

determination that ANDA applicants for generic metaxalone could carve out the food effect labeling from their proposed product labels. Of course, Mutual's 180-degree change of position would only serve to delay FDA approval of generic metaxalone (even for itself) and was submitted as part of the King-Mutual conspiracy.

177. Mutual's December 8, 2005 submission had no merit. It referred to no clinical studies demonstrating actual clinical effects, the only kind of information the FDA indicated would be necessary for any hope of success in its March 1, 2004 decision. Instead, Mutual only pointed to the clinically-inconsequential metabolism data it had created earlier that year. But these studies were not designed to demonstrate, and could not demonstrate, any clinically meaningful therapeutic (safety or effectiveness) information, nor even any legitimate concern for such information. And Mutual's speculation that drug-to-drug interactions might occur if the patient was taking another drug that impacts the P450 sub enzyme were just that – speculation. Mutual's letter simply presented *in vitro* data, and a hypothetical concern about drug-to-drug interactions that had no basis in supporting data or historical fact given the forty-plus year experience with metaxalone.

178. To make matters worse, Mutual's December 2005 letter to the FDA deceptively characterized Mutual's motives in sending the data to the FDA. Mutual claimed it was motivated to submit the three studies to the FDA for its consideration in "assessing the significance of the metaxalone food-effect." In fact, Mutual's change of heart was the direct result of the formation of the King-Mutual conspiracy, not the handful of small, clinically inconclusive studies, the significance of which it was misrepresenting to the FDA. And while Mutual footnoted the fact that it had licensed "this new safety data" to King (and no, it was not "safety data"), Mutual withheld from the FDA the true nature of its broad-based relationship

with King to delay generic entrants and share the monopoly profits in the meantime. Mutual did not tell the FDA that King agreed to pay Mutual $35 million plus royalties on all sales of branded Skelaxin. Instead, Mutual misleadingly emphasized that it had an ANDA pending for generic metaxalone, but did not inform the FDA that it had no intention of actually bringing a generic metaxalone to market.

179. Mutual knew the submission was baseless. No reasonable petitioner could have realistically expected the FDA to base important decisions about clinical therapeutic consequences on the *in vitro* metabolism data and speculative concerns raised by Mutual.

3. In February 2006, King and Mutual conspire and work to delay generic competition through the procuring and listing the '566 Patent.

180. Mutual also followed King's delay strategy by seeking a patent on the natural phenomenon inherent to the use of metaxalone, this time based on the metabolism studies.

181. On February 28, 2006, Mutual filed an application with the PTO to gain patent protection for its metaxalone metabolism data. The claims (variously phrased, and somewhat changed during prosecution of the patent) combined (i) the administration of metaxalone with (ii) information that metaxalone affects activity of the cytochrome P450 sub enzyme, such that (iii) if someone is taking another drug that also affects the P450 sub enzyme, there might be an effect on metaxalone bioavailability.

182. On October 17, 2006, the PTO issued patent number 7,122,566 (the "'566 Patent") to Mutual, which claimed methods of providing a patient with metaxalone and informing the patient about the potential for metaxalone to interact with drugs or foods that inhibit or induce the enzymes that metabolize metaxalone.

183. According to plan, Mutual then licensed the ’566 Patent to King pursuant to the King-Mutual Agreement. King then listed the ’566 Patent in the Orange Book as covering Skelaxin. All putative generic filers were now required to certify as to the ’566 Patent and potentially face additional patent infringement lawsuits, which placed another potential hurdle in the path to bringing a generic metaxalone product to market.

184. King knowingly listed the ’566 Patent, an ineligible patent, in the Orange Book. King deliberately and knowingly misused the FDA’s Orange Book listing process with respect to the ’566 Patent in an effort to exclude AB-rated generic competition to Skelaxin.

185. The ’566 Patent was invalid as obvious over the prior art. Enzyme metabolism information of the type set out in the ’566 Patent was known in the prior art for years prior to the application for the ’566 Patent. The prior art included FDA guidances issued in 1997 and 1999 that recommended that manufacturers of new and existing drugs incorporate in their labels the results of the very type of enzyme tests that formed the basis of the ’566 Patent. It was obvious to conduct tests that the FDA recommended and to then instruct patients about the results of those tests. And the data, in any event, simply described the natural phenomenon of some enzymatic interactions of metaxalone; it did not support any clinically consequential implications for the safe or effective use of metaxalone.

4. Throughout 2006, King and Mutual conspire and work to create the misimpression of an ongoing adversarial relationship by falsely maintaining patent infringement litigation they had no intention of pursuing.

186. As new partners in crime, King and Mutual recognized the pending patent infringement litigation between them as both an opportunity and a concern. At bottom, the litigation process had to be derailed. The parties were mere months from summary judgment and trial and the eventual result would be a court ruling that the ’102 and ’128 Patents were invalid;

that (in turn) would trigger the ability of other would-be generic manufacturers to obtain similar rulings and launch competing products. But if King and Mutual dismissed the case, their deal – the $35 million payment and the "royalties" – would be exposed for what it was: payoffs to Mutual for giving up the patent fight and helping delay generic entry.

187. So King and Mutual chose subterfuge. They would maintain the lawsuit on the docket but stay further proceedings and conceal their agreement from the court. Mutual would drop its effort to launch a competing generic metaxalone. And they would tag team their abuse of the citizen petition process with the FDA to slow the approval process for other would-be generic competitors.

188. King and Mutual did not inform the judge presiding over the Mutual '102 litigation about their agreement. Doing so would have raised a red flag about whether that action should be dismissed for lack of a justiciable controversy.

189. Instead, on May 15, 2006, King and Mutual filed a stipulation under seal to perpetuate the litigation and caused the court to place the litigation in civil suspense two days later "pending outcome of an FDA decision." King and Mutual filed the stipulation just in the nick of time – five months before the October 17, 2006 trial date, three months before summary judgment motions were due to be filed, one month before the FDA's thirty-month stay on the approval of Mutual's ANDA was set to expire, and just two days before expert reports were to be exchanged. The pending "FDA decision" the court (and, assumedly, the stipulation) referenced concerned whether the FDA would reconsider its clear and comprehensive March 1, 2004 decision that the generic products could "carve out" of their labels the indications claimed in the '128 Patent via Section VIII statements.

190. Had Mutual not been colluding with King, it would have pressed ahead with the litigation and sought invalidation of the '102 Patent. But because of the King-Mutual Agreement, Mutual changed from a potential generic competitor (one preparing to "market its metaxalone tablets (400 mg) as soon as it [was] permitted to do so" and "aggressively defend[ing] against any baseless lawsuit filed by King"), to King's co-conspirator (one bent upon maintaining King's monopoly as long as possible to share in King's monopoly profits).

191. Suspending the Mutual '102 litigation (rather than settling and terminating it) furthered the King-Mutual conspiracy by enabling Mutual to continue to appear to be King's adversary. In truth, the two companies were pursuing a concerted campaign of filing meritless petitions to delay the approval of any generic metaxalone product. Mutual and King intended the cloak of litigation to mask Mutual's participation in King's scheme to unlawfully maintain its monopoly. It did. The continued, but stayed, Mutual '102 litigation delayed the FDA's approval of the multiple filed ANDAs for generic metaxalone.

192. Additionally, by mischaracterizing their unlawful agreement as an ostensibly legitimate licensing agreement, King and Mutual misled the FTC, to which they were required to submit the agreement under the Medicare Modernization Act.[26] While Mutual had years earlier warned King that its action might be questioned by the FTC, now Mutual worked with King to avoid antitrust scrutiny.

193. King and Mutual misled the Eastern District of Pennsylvania by continuing to maintain the appearance of the Mutual '102 litigation long after Mutual actually abandoned any genuine effort to challenge the '102 Patent and market generic metaxalone. Mutual no longer

[26] 21 U.S.C. § 355 note (2003) ("Federal Trade Commission Review").

had any intention of invalidating the patent; doing so would be against its new interests under the agreement with King to share in King's monopoly profits.

194. While the Mutual '102 litigation had been a sham from the outset (as it had no likelihood of success), with Mutual's complicity in it, the case was now a concerted fraud on the court. Although there was no longer any justiciable controversy, both parties continued the litigation for an additional five years as a subterfuge to maintain their outward appearances – to the FDA, the FTC, and the public – as adversaries rather than conspirators.

195. Absent the King-Mutual Agreement, Mutual would have vigorously defended the Mutual '102 litigation. The result would have been invalidation of King's '102 Patent, either by summary judgment motions (due to be filed on August 2, 2006) or by trial (scheduled for October 2006). (As it was, the public would have to wait nearly three more years for such a ruling in the Eon '128 and '102 litigations.) Absent the King-Mutual Agreement, Mutual also would have pursued its efforts to obtain approval for generic metaxalone, ultimately entering the market with its generic metaxalone product.

196. Instead, Mutual has never pursued its ANDA filing for 400 mg metaxalone to final approval, never filed an ANDA for 800 mg generic metaxalone, and has never entered the market. Why? King paid Mutual not to do so.

5. King enters into an agreement with CorePharma in mid-2006.

197. On December 27, 2005, CorePharma amended its metaxalone ANDA to seek approval for 800 mg tablets, adding a Section VIII certification that the '128 Patent did not claim a use for which CorePharma was seeking approval. King never filed suit against CorePharma over the 800 mg ANDA. Instead, on May 11, 2006, King and CorePharma entered into a Manufacturing and Supply Agreement, CorePharma became King's "authorized distributor" and

would manufacture and supply 800 mg metaxalone tablets to King. However, the CorePharma '102 litigation over the 400 mg metaxalone tablet continued for nearly two more years, at which time King and CorePharma settled the litigation and CorePharma became King's authorized distributor of generic metaxalone.

6. The FDA approves the addition of age and gender food effects to Skelaxin's label in November 2006.

198. On November 24, 2006, the FDA granted final approval to King's April 2003 sNDA which sought to add information to the Skelaxin label about two studies designed to demonstrate the effects of age and gender on the bioavailability of Skelaxin. The new label noted "the pharmacokinetics of metaxalone are significantly more affected by age under fasted conditions than under fed conditions, with bioavailability under fasted conditions increasing with age." As for gender, the label now stated that "the bioavailability of metaxalone was significantly higher in females compared to males."

199. The final revisions did not recommend Skelaxin be taken with food nor did they contain anything regarding increased bioavailability based on age or gender having any clinical effect on safety or efficacy.

7. In February 2007, King persists in filing sham petitions with the FDA.

200. On February 13, 2007 (and in furtherance of the King-Mutual conspiracy), King filed a supplement to its March 18, 2004 petition seeking to prohibit any potential competitor from carving out the food effect information from the label for generic metaxalone. King argued that the carve out issue had been rendered moot by the Orange Book listing of the '102 Patent and new labeling finally approved in November 2006 that added language about the effects of age and gender on the bioavailability of Skelaxin. King also claimed that since the new

precaution section of the label specifically cross-referenced the pharmacokinetic information in the clinical pharmacology section, omission of that information would render the drug less safe.

201. This petition was baseless. First, the '102 Patent was invalid and King knew this. Second, as before, King's safety arguments were not supported by the types of studies that the FDA referred to in its March 1, 2004 decision (i.e., studies demonstrating actual clinical effects). Instead, King cited the same studies it had previously submitted as well as recent studies conducted by Mutual, none of which were designed to demonstrate any actual clinical or safety effects. Third, King cited Mutual's change of position as reflected in its December 8, 2005 submission – but King did not tell the FDA that Mutual now was receiving royalties from King for sales of branded Skelaxin and that Mutual was now directly benefiting from keeping generic competitors, including itself, off the market. Thus, King's February 13, 2007 submission was baseless, and no reasonable petitioner could have expected to succeed on that request.

8. In May 2007, Mutual again supports King and thwarts generic metaxalone competition, filing a sham petition with the FDA.

202. Continuing the tag-team approach, on May 2, 2007, Mutual submitted comments in support of King's February 13, 2007 supplemental petition. Mutual stated that it "supports King's position in its supplement that the food effect information contained in King's revised labeling for Skelaxin cannot be 'carved out' of the labeling for generic metaxalone," relying primarily on "additional confirmatory data that Mutual has developed since its December 8, 2005 submission to FDA." The additional data comprised two studies "consistent with the data previously submitted in December 2005 by Mutual to FDA."

203. This submission, like the others, was baseless. The additional study relied upon by Mutual was not designed to, and did not, demonstrate any clinical impact on either safety or

efficacy. As the FDA later reiterated, to demonstrate merit, the submission would need to present "[d]ata from at least one adequately designed clinical study that demonstrate[d] the relationship of dose and exposure of metaxalone on safety and efficacy parameters." Mutual's study did not. No reasonable petitioner would have expected success on this petition. As it had accused King of doing in 2004 prior to entering into the King-Mutual conspiracy, Mutual was now attempting to turn "a handful of small, clinically inconclusive bioavailability studies into an additional long-term barrier to generic competition."

204. And Mutual persisted with the façade that its actions were wholly independent of King, and done in the interest of patient safety. To mislead the FDA, Mutual reminded the FDA that "Mutual has an Abbreviated New Drug Application ('ANDA') for a generic version of Skelaxin pending before FDA (No. 40-536)" and recounted its efforts in 2001 to convince the FDA to require in vivo fasted studies from all ANDA applicants, noting "Mutual's concerns regarding safety issues with metaxalone are longstanding." But Mutual did not tell the FDA that it was now profiting from King's branded Skelaxin sales, and that it no longer intended to pursue its own ANDA for generic metaxalone.

9. Mutual makes still more baseless submissions to the FDA in mid-2007 and early 2008.

205. Furthering the conspiracy with King, Mutual continued to make baseless submissions to the FDA through 2007 and early 2008. None of them even purported to present reliable clinical information demonstrating an issue of safety or efficacy. Each was intended only to further tax an already overburdened and resource-deprived FDA to delay approval of ANDAs for generic metaxalone.

206. On July 27, 2007, Mutual petitioned the FDA to request the agency require the Skelaxin label include information relating to the effects of P450 liver sub enzymes on metabolizing metaxalone. Mutual relied primarily on the same study it had offered as part of its May 2, 2007 submission, one that, like the 2005 studies Mutual submitted, apparently but simply confirmed which enzymes metabolize metaxalone. The study did not demonstrate any clinical safety effect; rather, Mutual speculated as to what it might mean.

207. Mutual filed another citizen petition on January 22, 2008, requesting that the FDA not approve any ANDAs for generic metaxalone "until appropriate studies are performed to assure that product administration and generic substitution can occur without adverse clinical outcomes." As with the prior submissions, Mutual relied primarily on a metabolism study that showed clinically inconsequential information about which particular sub enzymes may play roles in metaxalone metabolism.

208. Both of these submissions were baseless. As with the previous studies proffered by Mutual and King, Mutual's study did not, by design, demonstrate any actual clinical therapeutic information. Mutual's submissions did not include the type of "adequately designed clinical study that demonstrate the relationship of dose and exposure of metaxalone on safety and efficacy parameters" that the FDA had indicated it would require. No reasonable petitioner would have expected to succeed on these petitions. Again, Mutual (as it had accused King of doing in 2004 prior to entering into the King-Mutual Agreement) was attempting to turn "a handful of small, clinically inconclusive bioavailability studies into an additional long-term barrier to generic competition."

209. Of course, in both submissions, Mutual reminded the FDA of its pending ANDA for generic metaxalone but not of the fact that it was receiving a percentage of Skelaxin sales from King and no longer intended to bring generic metaxalone to market.

10. In January 2008, King buys off CorePharma's patent challenge.

210. On January 2, 2008, King and CorePharma settled the patent litigation over CorePharma's ANDAs for 400 mg generic metaxalone. As part of the settlement and to "resolve all potential disputes between [them] with respect to Core[Pharma]'s 800 mg generic version," King granted CorePharma the right to enter the market as an "authorized generic" version of Skelaxin on the earlier of December 1, 2012 (approximately nine years before the expiration of King's patents) or the first sale of an 800 mg generic metaxalone by competitor (under certain conditions). The agreement allowed CorePharma to launch immediately should a competitor market, distribute, or sell generic metaxalone following a decision by a court that the asserted patents are invalid or the expiration of the FDA's thirty-month stay precluding it from granting final approval to a competitor.

211. The January 2008 agreement specified that King would supply CorePharma with the active pharmaceutical ingredient for the authorized generic, and CorePharma would manufacture and sell the authorized generic and pay King a distribution fee on such sales.

11. In July 2008, the FDA denies the King and Mutual petitions.

212. On July 18, 2008, the FDA denied Mutual's July 2007 and January 2008 petitions. The result was obvious and predictable from the face of the petitions: neither even purported to present any clinically meaningful data. The FDA observed that Mutual's evidence was based "solely on in vitro data and theoretical concerns" and Mutual "ha[d] not provided any evidence for your hypothesis that . . . changes in metaxalone exposure would lead to clinically

meaningful changes in the safety or efficacy of metaxalone products." "Such evidence," the FDA noted, "is critical for our consideration of your requests." To the FDA (and any reasonable person in this field), the information in Mutual's petitions was not even of the type that could justify a need for the additional clinical testing Mutual sought to impose on ANDA applicants.

213. Mutual's demand that the FDA require drug-to-drug interaction studies did not even pass the straight-face test: Mutual, the FDA pointedly stated, "fail[ed] to explain why clinical [drug-to-drug interaction] studies of Skelaxin must be performed at this time given that Skelaxin has been marketed in the United States for over 45 years with about 4 million prescriptions dispensed yearly since 2001 and without significant toxicities." Observing that no patients in three safety and efficacy studies or four pharmacokinetic studies of Skelaxin developed a serious adverse event or a level of toxicity deemed concerning, and that a review of the FDA's Adverse Events Reporting System and literature "revealed a scarcity of serious adverse events associated with use of Skelaxin," the FDA concluded "there is no evidence that higher metaxalone exposure would lead to increased Skelaxin toxicity."

214. Slamming the door on Mutual, the FDA reiterated "For us to consider requiring your proposed studies, you would have to provide us with . . . safety-related evidence" such as "data from at least one adequately designed clinical study that demonstrate the relationship of dose and exposure of metaxalone on safety and efficacy parameters" or "data that demonstrate the relationship between concomitant administration of Skelaxin with and without specific cytochrome P450 inhibitors and/or inducers and the pharmacokinetics, safety, and efficacy of Skelaxin in patients with acute musculoskeletal conditions."

215. In short, the FDA confirmed Mutual's studies were of the same character ("a handful of small, clinically inconclusive bioavailability studies") as those Mutual had warned the

FDA in 2004 to be wary of due to their potential use as an anticompetitive monopoly protecting device.

12. In late 2008, King and Mutual conspire and actively work to delay generic competition through meritless '566 Patent litigation against Sandoz.

216. On November 5, 2008, Sandoz amended its ANDA for 800 mg generic metaxalone and added a Paragraph IV certification that the '566 Patent was invalid or would not be infringed.

217. On December 5, 2008, King and a wholly-owned subsidiary of Mutual called Pharmaceutical IP Holding, Inc. (referred to below as "Mutual") commenced litigation against Sandoz in the United States District Court for the District of New Jersey in response to Sandoz's Paragraph IV certification as to the '566 Patent (the "Sandoz '566 litigation").

218. No reasonable litigant would have expected to succeed on the merits of the Sandoz '566 litigation. Numerous prior art references dating back to the 1990s rendered the patent invalid as obvious. King and Mutual's initiation of the '566 Patent litigation was baseless.

13. In January 2009, the *Eon '128 and '102 litigations* come to a predictable end: invalidation of the '128 and '102 Patents.

219. On January 20, 2009, Judge Trager of the Eastern District of New York granted summary judgment to Sandoz in the Eon '128 and '102 litigations, finding that the '128 and '102 Patents, "which are directed to methods of informing patients about and administering the muscle relaxant metaxalone," were invalid as inherently anticipated and/or obvious.[27] Reflecting the strength of the motion and obvious invalidity of the underlying patents, Sandoz won on the barest of records; as King noted in its brief in opposition to the motion for summary judgment, other than the relevant pieces of prior art:

[27] *King Pharms., Inc. v. Eon Labs, Inc.*, 593 F. Supp. 2d 501 (E.D.N.Y. 2009).

> [Sandoz's] *entire summary judgment record* consists of just 13 exhibits . . . . [It] does not contain a single sentence of deposition testimony or a single sentence from any expert via an affidavit explaining the disclosures of the six technical publications that underlie [Sandoz's] invalidity motion. Instead, [Sandoz] offers only attorney argument in its brief.

220. Though relying on prior art, the text of the patents, the case law and the attorneys' arguments, the court substantially grounded its opinion in the following observation:

> For over forty years it has been known to give metaxalone with food. The fact that King discovered a naturally occurring side effect to the known practice of administering metaxalone with food does not entitle it to a valid patent. "Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent."

221. The '128 and '102 Patents, directed to methods of informing patients about the pharmacokinetic effects of taking metaxalone with food, were invalid as inherently anticipated and/or obvious. At least six prior art references, several dating back to the 1960s, disclosed the relevant elements of the '102 and '128 Patents, namely, that metaxalone be taken with food. Millions of patients had been taking Skelaxin four times a day, with and without food, for decades. Indeed, the label instructed patients to take 800 mg of metaxalone three to four times a day without any instruction to take it with or without food. Since at least 1995, nurses had been instructed in "Clinical Drug Therapy, Rationales for Nursing Practice" to "[g]ive . . . metaxalone with milk or food" and to teach clients to "take the drugs with milk or food." There was nothing novel about the '102 or '128 Patents.

222. No reasonable litigant would have expected success on the merits of the Eon and CorePharma '128 and '102 litigations.[28] King's continued maintenance of the '128 Patent

[28] King consolidated its suits against Eon/Sandoz and CorePharma in 2003 but resolved claims against CorePharma in early 2008 when the two companies entered into an agreement allowing CorePharma to market and sell an authorized generic of Skelaxin. *See supra* Section Facts, D.9.

litigation against Eon and CorePharma after purchasing the Skelaxin franchise in June 2003 was baseless; it should have withdrawn the lawsuits relating to the '128 Patent after it purchased the Skelaxin franchise. King's initiation of patent litigation against Eon and CorePharma over the '102 Patent was baseless; it should never have initiated such litigation.

223. Rather, the patent infringement lawsuits pursued by King against Eon/Sandoz and CorePharma were "shams," pursued solely to block generic metaxalone competition.

14. In May 2009, Mutual files a last gasp petition with the FDA claiming misbranding.

224. Set back by Judge Trager's decision invalidating the '128 and '102 Patents, Mutual made one more attempt to delay entry of generic metaxalone, filing yet another baseless citizen petition on May 13, 2009.

225. Struggling for air, the petition recited a litany of requests for action by the FDA designed only to slow down and obstruct FDA approval of generic metaxalone. For example, Mutual asked for the FDA to declare Skelaxin to be "misbranded" unless King updated its label to reflect that Skelaxin is a delayed release dosage form and to require King to "perform pharmacokinetic study on crushed versus whole Skelaxin tablets, to discern the effects of crushing." For support, Mutual relied on three bioequivalence studies that were not designed to demonstrate any clinical therapeutic (safety or effectiveness) effect.

226. In reality, Mutual had no interest in the FDA declaring Skelaxin to be "misbranded;" that would put the Skelaxin sales Mutual was receiving royalties on at risk. Again, Mutual failed to inform the FDA that it had a direct financial stake in delaying market entry of generic metaxalone and that Mutual no longer had any intention of bringing a generic to

market. Instead, in a now familiar continuation of its subterfuge, Mutual again reminded the FDA that it had an ANDA for generic metaxalone pending since 2003.

227. The May 13, 2009 submission was baseless and intended simply to further the King-Mutual conspiracy and delay potential generic competition. No reasonable petitioner could have expected to succeed on that request.

E. 2010: things begin to fall apart for King and Mutual.

1. In the spring of 2010, Sandoz (Eon's successor) receives final FDA approval and launches generic metaxalone.

228. On March 30, 2010, recognizing that the '128 and '102 Patents had been found invalid, the FDA gave Sandoz a green light and approved its ANDA for the marketing and sale of generic metaxalone in 800 mg tablets. Sandoz's ANDA for generic metaxalone was first to be approved since the drug entered the market in 1962, 48 years earlier.

229. In the approval letter, the FDA commented on the more than five year delay between Sandoz's November 2004 application for approval and the March 2010 granting of it: "during the entire time the ANDA was under review, the agency had pending before it [King's] citizen petition [supported by Mutual] that created a review of the appropriate labeling for generic metaxalone in light of certain patent-protected language in the labeling of the RLD."

230. FDA approval was one hurdle but Sandoz faced another: it remained embroiled in King's sham infringement litigation over the '566 Patent filed in December 2008.[29] Despite this, Sandoz prepared for immediate, at-risk launch of generic metaxalone.

[29] *King Pharms., Inc., et al. v. Sandoz, Inc.*, C.A. No. 08-cv-05974 (D.N.J. Feb. 17, 2011) (Brown, J.).

231. King and Mutual sought to enjoin Sandoz's launch, filing a motion for a preliminary injunction on April 1, 2010 in the Sandoz '566 litigation. Judge Garrett Brown initially issued an order to show cause on April 1, 2010, temporarily restraining Sandoz from launching. On April 6, Judge Brown modified the order, scheduling argument on the motion for a preliminary injunction for April 14, 2010 but noting the temporary restraining order would be "immediately vacated upon any re-launch of a competing metaxalone product by CorePharma, Inc."

232. CorePharma's January 2008 agreement with King granted it the right to launch an authorized generic of Skelaxin once another generic manufacturer commenced the marketing, distribution, or sale of 800 mg metaxalone. On April 9, 2010, King's counsel notified Sandoz that CorePharma was launching its authorized generic that day. CorePharma's launch resulted in dissolution of any court restrictions on Sandoz and Judge Brown vacated the temporary restraining order on April 9, 2010.

233. Sandoz immediately entered the market with its generic metaxalone. (King sued CorePharma for breach of contract on April 13, 2010 and sought to enjoin CorePharma from selling the authorized generic. On May 6, 2010, the court (the same judge overseeing the Sandoz 566 litigation) granted King's request for a preliminary injunction barring CorePharma from selling generic metaxalone until a resolution of the action on the merits. Approximately six weeks later, King dismissed the suit voluntarily.)

234. On May 17, 2010, Judge Brown denied King and Mutual's motion for a preliminary injunction, finding Sandoz had "raised a 'substantial question' regarding patent validity and infringement" sufficient to defeat the injunction.

2. SigmaPharm sues King and Mutual over their conspiracy in April 2010.

235. At the same time, SigmaPharm, a company engaged in the business of the development of pharmaceutical technologies and products and that worked with King in developing generic versions of Skelaxin, sued King and Mutual. On April 19, 2010, SigmaPharm filed suit against King and Mutual in the Eastern District of Pennsylvania, alleging they conspired together and illegally restrained trade in violation of the federal Sherman Act and various state laws prohibiting unlawful restraint of trade.

236. In the complaint, SigmaPharm alleged King and Mutual were continuing to deceptively perpetuate the Mutual '102 litigation over whether Mutual's long-dormant ANDA infringed the '102 Patent, as part of the conspiracy to suppress competition from generic metaxalone, noting that King had taken no steps to prosecute that action since May 2006. In fact, King and Mutual had not even informed the Mutual '102 litigation court that the '128 and '102 Patents had been declared invalid by Judge Trager more than a year earlier, in January 2009, in the Eon '128 and '102 litigation.

237. On August 2, 2010 and at the court's request, Mutual submitted a status report in the Mutual '102 litigation. Only then did Mutual inform the court of the January 2009 ruling by Judge Trager finding the '128 and '102 Patents invalid. But, Mutual noted, the parties could not determine whether or how to proceed in the Mutual '102 litigation until the Federal Circuit resolved the pending appeal of Judge Trager's decision; Mutual recommended the action remain on the Court's suspense docket pending a decision by the Federal Circuit.

3. The Federal Circuit affirms the invalidity of the ’128 and ’102 Patents in August 2010.

238. That very same day, the Federal Circuit affirmed Judge Trager’s opinion and the invalidity of the ’128 and ’102 Patents.[30] The Federal Circuit agreed that at least three of the prior art references cited by the District Court each inherently anticipated the ’102 Patent’s food effects claims. As the Federal Circuit explained:

> As taught by the ‘128 Patent, the only steps required to increase metaxalone’s bioavailability are (1) ingesting metaxalone (2) with food. These steps are inherently disclosed by the prior art. An increase in bioavailability is, therefore, an inherent aspect of the prior art. . . . *To hold otherwise would remove from the public a method of treating muscle pain that has been performed for decades.*[31]

239. The Federal Circuit further concluded that King’s “informing” claim was also inherently anticipated. An inherently anticipated claim, the Federal Circuit reasoned, could not be rendered novel merely by requiring that the patient be told about the existence of an inherent property. The “informing” limitation, the Federal Court ruled, “adds no novelty to the method.”[32]

240. Eight days later, on August 10, 2010, King and Mutual informed the court in the Mutual ’102 litigation that the Federal Circuit had affirmed the invalidity of the ’102 Patent and that the parties did not oppose dismissal of the action “after sufficient time to insure that any issues on rehearing or rehearing en banc are resolved.” The court dismissed the Mutual ’102 litigation on March 29, 2011.

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[30] *King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267 (Fed. Cir. 2010).

[31] *Id.* at 1276 (emphasis added) (citations omitted).

[32] *Id.* at 1278.

241. Following the Federal Circuit's affirmance of the invalidity of the patents in August 2010, Sandoz moved for attorneys' fees in the Eon '128 and '102 litigations under 35 U.S.C. § 285. Sandoz asserted that King had withheld material information from the PTO in pursuing the '128 and '102 Patents, and commenced the infringement litigation intentionally without any reasonable likelihood of success.

242. Judge Trager found, among other things, that the prior art disclosing the effect of taking metaxalone with food – not disclosed to the PTO – was material.[33] He also found that King was "more concerned with preventing generic competition for Skelaxin than it was for improving the safety or efficacy of the drug, despite [King's] outward appearance that its primary concern was for 'good science.'" For example, Judge Trager noted, in response to a July 2001 email describing one of the "key objective[s]" of the life cycle management team as "delaying generic entry," senior King executives warned that such comments were "'legally unacceptable,'" advising "'[w]e can think it, say it, but not write it.'"[34]

243. Judge Trager ultimately ruled that Eon had failed to prove, by the heightened standard of "clear and convincing evidence," that King intended to defraud the PTO or initiated and litigated the 800 mg action despite knowing that its claims were frivolous.[35] But Judge Trager's decision was limited by the record in that action, which did not include much of the evidence cited herein concerning King's knowledge and motivation. King's agreement with Mutual and its campaign of filing baseless citizen petitions with the FDA in order to delay

[33] *King Pharmaceuticals, Inc. v. Eon Labs, Inc.*, 2010 U.S. Dist. LEXIS 102740 (S.D.N.Y. Sept. 28, 2010), at *28.

[34] *Id. at* *40-41.

[35] *Id.*

generic competition, when coupled with the record in the case before Judge Trager, demonstrate overwhelmingly that the Eon ’128 and ’102 litigation was baseless.

4. In late 2010, the *Sandoz ’566 litigation* comes to its predictable end: a jury verdict finding the ’566 Patent invalid.

244. On September 7, 2010, and without the filing of summary judgment motions, a jury trial commenced in the Sandoz ’566 litigation. On September 16, 2010, the jury reached unanimous verdicts for Sandoz on all counts, holding Sandoz neither directly infringed nor induced infringement on the ’566 Patent and that the ’566 Patent was invalid both on obviousness grounds and as anticipated by the prior art.

245. On October 18, 2010, King and Mutual filed a motion for judgment as a matter of law or for a new trial. Judge Brown denied the motion in a written opinion on February 17, 2011.

246. In the opinion, the court observed “there was evidence that [King’s licensing of Mutual’s ’566 Patent] was related to King’s attempt to maintain a monopoly in the market on metaxalone and not the innovative nature of the patent. [King’s former Executive Vice President of Corporate Affairs] Mr. Green admitted that one of his concerns prior to the license was preventing generic competitors from entering the market and that, at the time, Mutual had proposed a generic product. He also admitted that King had managed to keep generics such as Mutual off the market until Sandoz’s entry during the lawsuit.” Thus, the Sandoz court found, “[a] reasonable jury could have concluded that the impetus behind the license was to keep Mutual off the market.”

247. On February 18, 2011, King and Mutual filed a notice of appeal of the jury verdict finding the '566 Patent invalid. They later withdrew the notice, terminating the appeal in September 2011.

F. Harm to Competition and Damages.

248. But for Defendants' overarching, anticompetitive scheme to delay generic metaxalone competition in the United States, in whole or in part, generic metaxalone would have been available in the United States far earlier than April 9, 2010, when it belatedly became available. But for Defendants' illegal conduct, generic metaxalone would have been available as early as November 4, 2005 (twelve months after Eon/Sandoz filed its ANDA for 800 mg metaxalone), and certainly before 2010, when Sandoz finally entered the market.

249. King, and then King and Mutual, engaged in this overarching, anticompetitive scheme intentionally and with the sole purpose of delaying generic competition.

250. Additionally, but for Defendants' illegal conduct, Mutual would have launched its own generic metaxalone product (with shared exclusivity), resulting in additional price competition for metaxalone.

251. But for Defendants' illegal conduct, Plaintiffs and members of the Class would have begun to pay less for their metaxalone requirements far earlier than April 9, 2010. As a result, Defendants, by their conduct, injured Plaintiffs and the Class by causing them to pay substantial overcharges—potentially hundreds of millions of dollars—on their purchases of metaxalone.

VI. MONOPOLY POWER AND MARKET DEFINITION

252. At all relevant times, King had monopoly power over metaxalone products because King had the power to maintain the price of metaxalone products (meaning Skelaxin in

all its forms and dosage strengths and AB-rated bioequivalent metaxalone products) at supracompetitive levels without losing substantial sales to non-metaxalone products.

253. A small but significant, non-transitory price increase for Skelaxin by King would not have caused a significant loss of sales so as to make the higher prices unprofitable.

254. Skelaxin does not exhibit significant, positive cross-elasticity of demand with respect to price, with any product other than AB-rated generic versions of Skelaxin.

255. Because of, among other reasons, its unique pharmacokinetic and safety profile as a muscle relaxant, Skelaxin is differentiated from all products other than AB-rated generic versions of Skelaxin.

256. King needed to control only Skelaxin and its AB-rated generic equivalents, and no other products, in order to maintain the price of Skelaxin profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Skelaxin would render King unable to profitably maintain its current monopoly prices of Skelaxin without losing substantial sales.

257. King also sold branded Skelaxin at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

258. Defendants have had, and exercised, the power to exclude generic competition to branded Skelaxin.

259. Defendants, at all relevant times, enjoyed high barriers to entry with respect to the market for metaxalone products.

260. To the extent that Plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant market is all metaxalone products - *i.e.*, Skelaxin (in all its forms and dosage strengths) and AB-

rated bioequivalent metaxalone products. During the period relevant to this case, Defendants have been able to profitably maintain the price of Skelaxin well above competitive levels.

261. The relevant geographic market is the United States and its territories.

262. King's market share in the relevant market was 100% until on or about April 9, 2010.

VII. MARKET EFFECTS

263. Sandoz began to ship generic Skelaxin to Plaintiffs and other members of the Class on or shortly after April 9, 2010, after receiving the FDA's formal, written final approval of its ANDA.

264. In its March 31, 2010 approval letter for Sandoz's ANDA, the FDA explained that its delay in approving Sandoz's ANDA was related to the citizen petition activity discussed above.

265. Defendants' anticompetitive scheme had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Skelaxin from generic competition. For example: but for King's sham litigation against Eon in connection with its Paragraph IV certification on the 800 mg formulation and its baseless citizen petitions, and but for the anticompetitive agreement between King and Mutual, their joint efforts to present the FDA with sham citizen petitions, and the simultaneous concerted fraud on the district court hearing their own patent litigation, Eon would have received final FDA approval and entered the market with a generic Skelaxin bioequivalent as early as November 4, 2005 (12 months—the maximum time it took the FDA to approve ANDAs like this at that time—after Eon's 800 mg metaxalone ANDA filing), and under all circumstances, on or about January 20, 2009 (when Eon won summary judgment of invalidity on the '102 and '128 Patents). Defendants' actions

allowed King to maintain a monopoly and exclude competition in the market for metaxalone products, leading to higher prices paid by Plaintiffs and all other members of the Class.

266. But for some or all of Defendants' overarching anticompetitive scheme, Eon/Sandoz or one or more other generic competitors would have begun selling AB-rated generic versions of Skelaxin sooner than April 9, 2010, when Eon/Sandoz launched. Specifically, but for Defendants' overarching anticompetitive scheme, in whole or in part, Eon/Sandoz or one or more generic competitors would have launched generic Skelaxin at least as early as November 4, 2005.

267. But for Defendants' illegal conduct, Mutual would have launched its own generic Skelaxin bioequivalent six months after Sandoz entered the market with its generic, thus forcing down the price of generic Skelaxin due to additional price competition.

268. But for Defendants' illegal conduct, Plaintiffs and members of the Class would have paid less for metaxalone far earlier than April 9, 2010, when Sandoz first entered the market with its generic. Defendants' conduct directly injured Plaintiffs and the Class by forcing them to pay hundreds of millions of dollars in overcharges on their metaxalone purchases.

269. As a result of the delay in generic Skelaxin competition brought about by Defendants' overarching anticompetitive scheme, in whole or in part, Plaintiffs and the Class paid more for metaxalone products than they would have paid absent Defendants' illegal conduct.

270. Eon/Sandoz and the other ANDA applicants seeking to market generic Skelaxin had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, manufacturing commercial launch quantities adequate to meet market demand,

marketing generic pharmaceutical products, and paying and receiving consideration for selective waiver and/or relinquishment of 180-day first-to-file marketing exclusivities.

271. Upon generic entry, generic versions of brand-name drugs are priced significantly below the branded drug to which they are AB-rated. As a result, upon generic entry, virtually all branded drug purchases are rapidly substituted for generic versions of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug fall even further because of increasing price competition.

272. This price competition enables all end-payors of the drugs to: (a) purchase generic versions of the drug at a substantially lower price than the brand; (b) purchase generic versions of the drug at a lower price; and/or (c) purchase the brand drug at a reduced price. Consequently, brand name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

273. If generic Skelaxin competitors had not been unlawfully prevented from entering the market earlier and competing with King, end-payors, such as Plaintiffs and members of the Class, would have paid less for metaxalone by (a) substituting purchases of less-expensive AB-rated generic Skelaxin for their purchases of more-expensive brand Skelaxin, (b) purchasing generic Skelaxin at lower prices sooner, and (c) purchasing brand Skelaxin at a reduced price.

274. Moreover, due to Defendants' conduct, other generic manufacturers were discouraged from and/or delayed in developing generic versions of Skelaxin.

275. Thus, Defendants' unlawful conduct deprived Plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure.

VIII. ANTITRUST IMPACT

276. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Skelaxin indirectly from King and/or purchased substantial amounts of AB-rated bioequivalent generic Skelaxin from Sandoz or others. As a result of Defendants' illegal conduct, members of the Class were compelled to pay artificially inflated prices for their metaxalone requirements. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic versions of Skelaxin sooner; and/or (2) the price of the available generic Skelaxin was artificially inflated by Defendants' illegal conduct.

277. As a consequence, Plaintiffs and members of the End Payor Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

278. Defendants' efforts to monopolize and restrain competition in the market for metaxalone have substantially affected interstate and foreign commerce.

279. At all material times, King manufactured, promoted, distributed, and sold substantial amounts of Skelaxin in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. Defendants' anticompetitive conduct had substantial instrastate effects in every state of purchase in that, inter alia, retailers within each state were foreclosed from offering cheaper generic Skelaxin to purchasers within each state and the generic foreclosure and delay directly impacted and disrupted commerce for consumers and third-party payors within each state.

280. At all material times, Defendants transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Skelaxin.

281. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. *See* Hovenkamp, FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE (1994) at 624. Professor Hovenkamp states that "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." Professor Hovenkamp also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."

282. Further, the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution are passed on to end-payors. Wholesalers and retailers passed on the inflated prices of Skelaxin and generic Skelaxin bioequivalents to the Plaintiffs and members of the End Payor Class.

283. King's anticompetitive actions enabled it to indirectly charge consumers and third-party payors prices in excess of what it otherwise would have been able to charge absent its unlawful actions individually and with Mutual.

284. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

285. The inflated prices that the End-Payor Class paid are traceable to, and the foreseeable result of, the overcharges by King and Mutual.

IX. CLASS ACTION ALLEGATIONS

286. Plaintiffs, on behalf of themselves and all Class members, seek damages, measured as overcharges, trebled, against Defendants based on allegations of anticompetitive conduct in the market for branded Skelaxin and its generic equivalents.

287. Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a), (b)(2), and (b)(3), as representatives of a Class defined as follows:

> All persons or entities in the United States and its territories who purchased and/or paid for some or all of the purchase price for Skelaxin and/or its AB-rated generic equivalents in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "Class"), other than for resale, during the period November 4, 2005 through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" Skelaxin or its generic equivalent if they paid or reimbursed some or all of the purchase price.

288. The following persons or entities are excluded from the proposed class:

a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal government entities, except for government funded employee benefit plans;

b. All persons or entities who purchased Skelaxin or its AB-rated generic equivalent for purposes of resale or directly from Defendants or their affiliates;

c. Fully insured health plans (*i.e.*, plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members);

d. Flat co-payers (*i.e.*, consumers who paid the same co-payment amount for brand and generic metaxalone); and

e. The judges in this case and any members of their immediate families.

289. Members of the Class are so numerous that joinder is impracticable. Plaintiffs believe that there are hundreds of thousands of Class members.

290. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of Defendants, *i.e.*, they paid artificially inflated prices for metaxalone and were deprived of the benefits of earlier and more robust competition from cheaper generic versions of Skelaxin as a result of Defendants' wrongful conduct.

291. Plaintiffs will fairly and adequately protect and represent the interests of the Class. The interests of the Plaintiffs are coincident with, and not antagonistic to, those of the Class.

292. Plaintiffs are represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

293. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

294. Questions of law and fact common to the Class include:

a. whether King willfully obtained and/or maintained monopoly power over Skelaxin and its generic equivalents;

b. whether King entered into a contract, combination, and/or conspiracy with Mutual to restrain trade and, if so, whether it should be evaluated under the rule of *per se* illegality, the "rule of reason," or some other rule or standard;

c. whether Defendants unlawfully excluded competitors and/or potential competitors from the market for metaxalone, *i.e.*, Skelaxin and its AB-rated generic bioequivalents;

d. whether Defendants unlawfully delayed or prevented generic manufacturers from coming to market in the United States;

e. whether Defendants maintained King's monopoly power by delaying generic entry;

f. whether the law requires the definition of a relevant market when direct proof of monopoly power is available and, if so, the definition of the relevant market;

g. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

h. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiffs and the members of the Class; and

i. the quantum of aggregate overcharge damages to the Class.

295. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated, geographically dispersed persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in the management of this class action.

296. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

X. FRAUDULENT CONCEALMENT TOLLING THE STATUTE OF LIMITATIONS

297. Plaintiffs and members of the Class had no knowledge of Defendants' unlawful self-concealing scheme and could not have discovered the scheme and conspiracy through the exercise of reasonable diligence more than four years prior to the filing of this Complaint.

298. This is so both because the nature of Defendants' conspiracy was self-concealing and because Defendants employed deceptive practices and techniques of secrecy to avoid detection of, and to fraudulently conceal, their contract, combination, conspiracy, and scheme. Notwithstanding the self-concealing nature of their conspiracy, Defendants and their co-conspirators wrongfully and affirmatively concealed the existence of their continuing combination and conspiracy from Plaintiffs by, among other things, concealing their plan to prolong the King-Mutual litigation despite the fact that Mutual had abandoned its effort to challenge King's patents and market generic metaxalone and even after the patents were invalidated in the King-Eon Litigation, filing under seal relevant filings in the various litigations (including those designed to delay the King-Mutual litigation), failing to promptly inform the court in the King-Mutual patent litigation that the patents had been invalidated in the King-Eon Litigation, agreeing to an arrangement whereby Mutual was paid a five percent royalty for the '566 Patent without disclosing that it would be due regardless of whether the patent ever issued or was found invalid, and maintaining the illusion of being adversaries in their citizen petition activities before the FDA.

299. Because the alleged conspiracy was both self-concealing and affirmatively concealed by Defendants and their co-conspirators, Plaintiffs and members of the Class had no knowledge of the alleged conspiracy, or of any facts or information that would have caused a

reasonably diligent person to investigate whether a conspiracy existed, until January 29, 2010 at the earliest, when SigmaPharm filed a complaint in the United States District Court for the Eastern District of Pennsylvania alleging a scheme to delay entry of generic metaxalone.

300. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting the Plaintiffs' and the Class's claims have been tolled.

XI. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
For Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Defendants' Violations of Sections 1 and 2 of the Sherman Act (Asserted Against All Defendants)

301. Plaintiffs incorporate by reference the preceding allegations and paragraphs.

302. Defendants knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme designed to block and delay entry of competing metaxalone formulations, *i.e.*, AB-rated generic versions of Skelaxin. The intended and accomplished goal of the scheme was to maintain King's monopoly power using restrictive and exclusionary conduct to delay FDA approval of ANDAs for generic metaxalone products. Defendants injured Plaintiffs and the Class through, inter alia, a series of sham citizen petitions, sham litigation, concerted fraud on the district court overseeing Defendants' own infringement case, and an agreement between King and Mutual to exclude Mutual's generic metaxalone product from the market in exchange for cash payments and royalties on the branded Skelaxin product.

303. Defendants' scheme specifically included, inter alia, the following events:

a. Wrongfully instituting and/or maintaining sham patent lawsuits against Mutual, Eon/Sandoz, and CorePharma over the '128, '102, and '566 Patents;

b. Wrongfully listing and maintaining the listing in the FDA's Orange Book of the '128, '102, and '566 Patents as claiming Skelaxin despite knowing that those patents were invalid and could not reasonably support a claim of infringement;

c. Wrongfully filing baseless citizen petitions with the FDA, including, but not limited to, the following submissions:

i. King's March 18, 2004 submission;

ii. King's May 13, 2004 submission;

iii. Mutual's December 8, 2005 submission;

iv. King's February 13, 2007 submission;

v. Mutual's May 2, 2007 submission;

vi. Mutual's July 27, 2007 submission;

vii. Mutual's January 2, 2008 submission; and

viii. Mutual's May 13, 2009 submission.

d. King paying Mutual in exchange for Mutual's agreement to: (1) stay out of the generic metaxalone market; (2) perpetuate the King-Mutual Litigation even though they had abandoned their adversarial positions; and (3) wrongfully file baseless citizen petitions with the FDA to delay and obstruct approval of generic metaxalone ANDAs.

304. King repeatedly asserted that the generic Skelaxin formulations of its competitors infringed its patents, despite knowing that the Skelaxin patents were invalid and/or unenforceable.

305. It was the Defendants' conscious object to further King's monopoly in the relevant market through the overarching anticompetitive scheme. Defendants conspired to

monopolize, and did wrongfully and intentionally maintain monopoly power, with respect to the market for metaxalone in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for their metaxalone requirements.

306. Had manufacturers of generic metaxalone products entered the market and lawfully competed with King in a timely fashion, Plaintiffs and other members of the Class would have substituted lower-priced generic metaxalone products for the higher-priced brand-name Skelaxin for some or all of their metaxalone product requirements, and/or would have paid lower net prices on their remaining Skelaxin and/or AB-rated bioequivalent purchases.

307. Defendants intended, and accomplished, a horizontal market allocation of the metaxalone market, a per se violation of Section 1 of the Sherman Act. By their agreement, Defendants intentionally and wrongfully conspired and combined in an unreasonable restraint of trade in violation of Section 1 of the Sherman Act. As a result of this unreasonable restraint on competition, Plaintiffs and members of the Class paid artificially inflated prices for their metaxalone requirements.

308. Although at least one generic version of Skelaxin has entered the market, Plaintiffs continue to suffer and will continue to suffer in the future from paying higher prices for Skelaxin and/or its AB-rated generic equivalents than they would have absent Defendants' anticompetitive conduct and continuing anticompetitive agreement.

309. Defendants' anticompetitive conduct is not entitled to qualified Noerr-Pennington immunity. The citizen petitions and infringement litigation were objectively baseless in that no reasonable litigant could expect success on the merits, and were subjectively in bad faith because Defendants used, and intended to use, these official processes solely as anticompetitive weapons.

310. Plaintiffs and members of the Class purchased substantial amounts of Skelaxin and/or AB-rated generic equivalents indirectly from King and/or other manufacturers.

311. Plaintiffs and the Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates Sections 1 and 2 of the Sherman Act.

312. Plaintiffs and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

SECOND CLAIM FOR RELIEF
For Monopolization Under State Law
(Asserted Against King)

313. Plaintiffs incorporate by reference the preceding allegations and paragraphs.

314. At all relevant times, King possessed substantial market power (*i.e.*, monopoly power) in the relevant market for metaxalone products. King possessed the power to control prices in, to prevent prices from falling in, and to exclude competitors from the relevant market.

315. Through the overarching anticompetitive scheme, as alleged extensively above, King willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, in order to exclude competition for its metaxalone product.

316. The goal, purpose, and effect of King's scheme was to prevent and delay the sale of metaxalone products in the United States at prices significantly below King's prices for Skelaxin, thereby effectively preventing the average market price of metaxalone products from declining dramatically.

317. By engaging in the foregoing conduct, King has violated the following state antitrust laws:

a. King has intentionally and wrongfully maintained monopoly power in the relevant market in violation of Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Arizona by members of the Class.

b. King has intentionally and wrongfully maintained monopoly power in the relevant market in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in California by members of the Class.

c. King has intentionally and wrongfully maintained monopoly power in the relevant market in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Florida by members of the Class.

d. King has intentionally and wrongfully maintained monopoly power in the relevant market in violation of Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Massachusetts by members of the Class.

e. King has intentionally and wrongfully maintained monopoly power in the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Michigan by members of the Class.

f. King has intentionally and wrongfully maintained monopoly power in the relevant market in violation of Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. §§ 8.31, *et*

seq., with respect to purchases of Skelaxin and AB-rated bioequivalents in Minnesota by members of the Class.

g. King has intentionally and wrongfully maintained monopoly power in the relevant market in violation of Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Mississippi by members of the Class.

h. King has intentionally and wrongfully maintained monopoly power in the relevant market in violation of Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Nebraska by members of the Class.

i. King has intentionally and wrongfully maintained monopoly power in the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in New Mexico by members of the Class.

j. King has intentionally and wrongfully maintained monopoly power in the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Nevada by members of the Class.

k. King has intentionally and wrongfully maintained monopoly power in the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in North Carolina by members of the Class.

l. King has intentionally and wrongfully maintained monopoly power in the relevant market in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Tennessee by members of the Class.

m. King has intentionally and wrongfully maintained monopoly power in the relevant markets in violation of W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in West Virginia by members of the Class.

n. King has intentionally and wrongfully maintained monopoly power in the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Wisconsin by members of the Class.

318. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic metaxalone products, sooner, and (2) paying higher prices for metaxalone products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws of the above States were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

319. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

THIRD CLAIM FOR RELIEF
For Conspiracy to Monopolize Under State Law
(Asserted Against All Defendants)

320. Plaintiffs incorporate by reference the preceding allegations and paragraphs.

321. On or before December 6, 2005, Defendants willfully and unlawfully entered a continuing illegal conspiracy to monopolize the metaxalone market, which lasted through at least April 9, 2010, in which Defendants engaged in an anticompetitive scheme to keep generic equivalents from the market. Defendants' extended monopolization period was not a result of providing a superior product, Defendants' business acumen, or historical accident.

322. The agreement between King and Mutual to monopolize the metaxalone market included overt acts between separate economic entities—actual and potential competitors—and is illegal per se under state antitrust laws. Alternatively, this Complaint alleges that the agreement and conspiracy to monopolize is a violation of state antitrust law under a "quick look" or "rule of reason" analysis.

323. The King-Mutual conspiracy included, but was not limited to, the following substantial steps by King and Mutual in furtherance of the conspiracy:

a. King's agreement with Mutual to forgo the marketing of a generic metaxalone product in exchange for substantial payments;

b. Perpetuating the King-Mutual Litigation in the United States District Court for the Eastern District of Pennsylvania without alerting the Court to Mutual's abandonment of any intent to market generic metaxalone or King's substantial payments to Mutual, and;

c. A joint campaign of filing baseless citizen petitions with the FDA to obstruct and delay approval of any generic metaxalone ANDA.

324. King and Mutual knowingly and intentionally conspired to maintain and enhance King's monopoly power in the relevant market.

325. King and Mutual specifically intended that the overarching anticompetitive scheme would maintain King's monopoly power in the relevant market, and they injured Plaintiffs and the Class thereby.

326. King and Mutual each committed at least one overt act in furtherance of the conspiracy.

327. Contrary to what would have been in its own unilateral economic self-interest in the absence of anticompetitive conspiracy, Mutual secured and licensed the '566 Patent to King in order to help King prolong its monopoly stranglehold on the metaxalone market when it was clear that the '102 and '128 Patents would be invalidated.

328. Contrary to what would have been in its own unilateral economic self-interest in the absence of the anticompetitive conspiracy, Mutual presented the FDA with a number of sham citizen petitions that were intended to, and did, delay approval of generic metaxalone.

329. By engaging in the foregoing conduct, Defendants have violated the following state antitrust laws:

a. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Arizona by members of the Class.

b. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in California by members of the Class.

c. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Florida by members of the Class.

d. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Kansas by members of the Class.

e. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Massachusetts by members of the Class.

f. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Michigan by members of the Class.

g. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Minnesota by members of the Class.

h. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Miss. Code Ann. §§ 75-21-3, *et*

seq., with respect to purchases of Skelaxin and AB-rated bioequivalents in Mississippi by members of the Class.

i. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Nebraska by members of the Class.

j. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in New Mexico by members of the Class.

k. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Nevada by members of the Class.

l. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of New York General Business Law §§ 340, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in New York by members of the Class.

m. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in North Carolina by members of the Class.

n. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Tennessee by members of the Class.

o. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant markets in violation of W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in West Virginia by members of the Class.

p. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Wisconsin by members of the Class.

330. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic metaxalone products, sooner, and (2) paying higher prices for metaxalone products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws of the above States were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

331. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations.

FOURTH CLAIM FOR RELIEF
For Conspiracy and Combination in Restraint of Trade Under State Law
(Asserted Against All Defendants)

332. Plaintiffs incorporate by reference the preceding allegations and paragraphs.

333. In 2005, King and Mutual entered into the Agreement, and Mutual joined King's overarching anticompetitive scheme as a co-conspirator. The Agreement is and was a contract, combination, and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which was to:

a. allocate all sales of metaxalone in the United States to King until April 9, 2010;

b. prevent Mutual's sale in the United States of a generic version of metaxalone; and

c. fix the price that Plaintiffs and members of the Class would pay for metaxalone.

334. The Agreement harmed Plaintiffs and the Class as set forth above.

335. The Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

336. The Agreement between Defendants is a horizontal market allocation and price fixing agreement between actual and potential competitors and is illegal per se under state antitrust laws. Alternatively, this Complaint alleges that the Agreement is an unreasonable restraint of trade, in violation of state antitrust law, under a "quick look" or "rule of reason" analysis.

337. There is and was no legitimate, non-pretextual, procompetitive business justification for the Agreement that outweighs its harmful effect. Even if there were such a justification, the Agreement is and was broader than necessary to achieve any conceivable procompetitive purpose.

338. By engaging in the foregoing conduct, Defendants have violated the following state antitrust laws:

a. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Arizona by members of the Class.

b. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq*., with respect to purchases of Skelaxin and AB-rated bioequivalents in California by members of the Class.

c. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Florida by members of the Class.

d. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Kansas by members of the Class.

e. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Massachusetts by members of the Class.

f. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Michigan by members of the Class.

g. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Minnesota by members of the Class.

h. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Mississippi by members of the Class.

i. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Nebraska by members of the Class.

j. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in New Mexico by members of the Class.

k. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Nev. Rev. Stat. Ann. §§ 598A.060,

et seq., with respect to purchases of Skelaxin and AB-rated bioequivalents in Nevada by members of the Class.

l. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of New York General Business Law §§ 340, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in New York by members of the Class.

m. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in North Carolina by members of the Class.

n. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Tennessee by members of the Class.

o. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trades in violation of W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in West Virginia by members of the Class.

p. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Wisconsin by members of the Class.

339. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic metaxalone products, sooner, and (2) paying higher prices for metaxalone products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws of the above States were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

340. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations.

FIFTH CLAIM FOR RELIEF
For Unfair And Deceptive Trade Practices Under State Law
(Asserted Against All Defendants)

341. Plaintiffs incorporate by reference the preceding allegations and paragraphs.

342. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and Class members were deprived of the opportunity to purchase a generic version of Skelaxin and forced to pay higher prices for their metaxalone requirements.

343. There was a gross disparity between the price that Plaintiffs and the Class members paid for the brand product and the value received, given that a much cheaper substitute generic product should have been available.

344. By engaging in the foregoing conduct, Defendants have violated the following state unfair and deceptive trade practices and consumer fraud laws:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code §§ 4-88-101, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Arkansas by members of the Class.

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq*., with respect to purchases of Skelaxin and AB-rated bioequivalents in California by members of the Class.

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Florida by members of the Class.

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Massachusetts by members of the Class

e. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. §§ 325F.68, *et seq*., and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Minnesota by members of the Class.

f. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Missouri Stat. §§ 407.010, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Missouri by members of the Class.

g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Nebraska by members of the Class.

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Pennsylvania by members of the Class.

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Rhode Island by members of the Class.

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases of Skelaxin and AB-rated bioequivalents in Virginia by members of the Class.

345. Plaintiffs and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Claim. Their injury consists of paying higher prices for Skelaxin and/or its AB-rated bioequivalents than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

SIXTH CLAIM FOR RELIEF
Unjust Enrichment
(Asserted Against All Defendants)

346. Plaintiffs incorporate by reference the preceding allegations and paragraphs.

347. Defendants have benefited from the monopoly profits on their sales of Skelaxin and/or its AB-rated bioequivalents resulting from the unlawful and inequitable acts alleged in this Complaint.

348. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Skelaxin and its AB-rated bioequivalents by Plaintiffs and members of the Class.

349. Plaintiffs and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiffs and the Class.

350. It would be futile for Plaintiffs and the Class to seek a remedy from any party with whom they had privity of contract. Defendants have paid no consideration to anyone for any benefits received indirectly from Plaintiffs and the Class.

351. It would be futile for Plaintiffs and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Skelaxin or its generic equivalents, as they are not liable and would not compensate Plaintiffs for unlawful conduct caused by Defendants.

352. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for Skelaxin and/or its generic equivalents is a direct and proximate result of Defendants' unlawful practices.

353. The financial benefits derived by Defendants rightfully belong to Plaintiffs and the Class, as Plaintiffs and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

354. It would be inequitable under unjust enrichment principles in Arizona, Arkansas, California, Florida, Kansas, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Mexico, New York, North Carolina, Pennsylvania, Rhode Island, Tennessee, Virginia, West Virginia, and Wisconsin for the Defendants to be permitted to retain any of the overcharges for Skelaxin and/or its AB-rated bioequivalents derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

355. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiffs.

356. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiffs and the Class all unlawful or inequitable proceeds received by them.

357. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiffs and the Class.

358. Plaintiffs and the Class have no adequate remedy at law.

XII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on behalf of themselves and the End Payor Class, demand judgment for the following relief:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a), (b)(2), and (b)(3), direct that reasonable notice of this action, as provided by Fed.

R. Civ. P. 23(c)(2), be given to the Class, and declare the Plaintiffs representatives of the End Payor Class;

B. Declare that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act, of the other statutes set forth above, and of the common law of unjust enrichment in Arizona, Arkansas, California, Florida, Kansas, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Mexico, New York, North Carolina, Pennsylvania, Rhode Island, Tennessee, Virginia, West Virginia, and Wisconsin;

C. Enjoin Defendants from continuing the illegal activities alleged herein;

D. Enter joint and several judgments against Defendants in favor of Plaintiffs and the End Payor Class;

E. Grant Plaintiffs and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

F. Award the End Payor Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

G. Award Plaintiffs and the End Payor Class their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and as the Court deems just.

XIII. JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiffs, on behalf of themselves and the proposed Class, demand a trial by jury on all issues so triable.

Dated: November 2, 2012

Respectfully submitted,

_/s/ James G. Stranch, III_____

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